

The following sample(s) was/were submitted and identified on behalf of the client as:

Applicant: AMBULANC (SHENZHEN) TECH. CO., LTD  
3rd Floor, Block C, Building #5 Skyworth Innovation Industry Park, Tang Tou  
1st Road, Shiyao, Baoan District, 518108, Shenzhen, China

Manufacturer: Same as applicant

Factory: Same as applicant

Laboratory: SGS-CSTC Standards Technical Services Co., Ltd. Shenzhen Branch  
No.1 Workshop, M-10, Middle Section, Science and Technology Park,  
Nanshan District, Shenzhen, Guangdong, 518057, China

Test standard(s): EN 1789:2020

Test item description: Automatic External Defibrillator

Model/Type reference: i7 Plus, i7e Plus, i9 Plus, i9e Plus, i7, i7e, i9, i9e

Ratings: Battery powered: DC12V, 4.5Ah

Test result: In the opinion of SGS-CSTC the presented equipments were found to be **in compliance with** the test specification as indicated in the details on the following pages.

Remark: None



  
Fly Lu  
Project Reviewer

  
Eric Wu  
Project Engineer

Medical Electrical Equipment Laboratory



**List of Attachments:**

Attachment 1: Static test method for clause 5.3 and 6.3.5  
Attachment 2: Photo documentation

**Summary of testing:**

Tests performed (name of test and test clause):  
Tests according to the following standard was carried out:  
**EN 1789:2020**  
The submitted samples fulfilled the requirements of specified standard.  
Clauses 5.3 and 6.3.5 were evaluated using the static test method (refer to attachment 1) provided by the applicant.  
  
Model i9 Plus was subjected to full test. Other models were subjected to construction review.

**Test Location:**

Except for clause 6.3.4:  
No.1 Workshop, M-10, Middle Section, Science and Technology Park, Nanshan District, Shenzhen, Guangdong, 518057, China  
  
For clau 6.3.4 Mechanical strength:  
198 Kezhu Road, Science City, Economic & Technology Development Area, Guangzhou, Guangdong, China

**Copy of marking plate:**

The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs or NBs that own these marks.



Label of i9 Plus

**Remarks:**

1. Height of WEEE logo shall not be less than 7 mm.
2. The marking plate of other models is identical to i9 Plus except for model name.



Test item particulars..... :  
 Classification of installation and use..... : Fixed equipment on ambulance  
 Supply connection..... : Internally powered

**Possible test case verdicts:**  
 - test case does not apply to the test object..... : N/A  
 - test object does meet the requirement ..... : P (Pass)  
 - test object does not meet the requirement ..... : F (Fail)

**Testing**  
 Date of receipt of test item..... : 2024-03-07  
 Date (s) of performance of tests..... : From 2024-03-07 to 2024-04-24

**General remarks:**  
 The test results presented in this report relate only to the object tested, this report shall not be reproduced, except in full, without the written approval of the Issuing testing laboratory.  
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 Throughout this report a  comma /  point is used as the decimal separator.

**General product information:**  
 The Automatic External Defibrillator provides CPR voice/animation guidance and instructs the user to perform external defibrillation for the treatment of suspected cardiac arrest patients (adults and pediatric patients) who are unresponsive, breathless, or have abnormal breathing and no signs of circulation. The adult mode is suitable for patients aged at least 8 years and the pediatric mode is suitable for patients under 8 years of age or weighing less than 25 kg. The product should be used in public or medical settings by personnel trained in CPR and AED use, or by medical personnel trained in basic life support and advanced life support courses, or under the guidance of emergency center dispatchers.  
 Protection against electric shock: Internally powered.  
 Protection against harmful ingress of water or particulate matter: IP65.  
 Model differences:  
 All the models are identical on circuit, critical components, and appearance structure, only the configuration differences as following table:

Model	The display screen is Equipped with a photosensitive sensor	Support for ECG waveform display	Color of the cover
i7 Plus	No	No	Semi transparent
i7e Plus	No	No	Yellow
i9 Plus	Yes	Yes	Semi transparent
i9e Plus	Yes	Yes	Yellow
i7	No	No	Semi transparent
i7e	No	No	Yellow
i9	Yes	Yes	Semi transparent
i9e	Yes	Yes	Yellow



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EN 1789:2020			
Clause	Requirement	Remarks	Verdict
<b>4</b>	<b>Requirements</b>		--
<b>4.1</b>	<b>General requirements</b>		--
	Road ambulances and equipment shall, when operated in normal use and maintained according to the instructions of the manufacturer, cause no safety hazard which could reasonably be foreseen using risk management procedures, e.g. in accordance with EN ISO 14971:2019, and which is connected with their intended application, in normal condition and in single fault condition.		P
<b>4.2</b>	<b>Electrical requirements</b>		--
<b>4.2.1</b>	<b>General</b>	Not road ambulance	N/A
	Electrical installations added to the base vehicle shall comply with those clauses of IEC 60364-7-721:2017 which are applicable to road ambulances. For the supply system of the medical equipment EN 60601-1:2006+A1:2013 and EN 60601-1-12:2015, Clause 11 shall apply.		N/A
<b>4.2.2</b>	<b>Electromagnetic compatibility (EMC)</b>		N/A
	In order to minimize the risk to the safe operation of the complete road ambulance and any of the equipment operated on or in the vehicle from the effects of electromagnetic influences: — Communication equipment (e.g. radio installation) shall comply with national and/or European regulations. — The complete operational vehicle shall consist of components, equipment or sub systems that comply or are certified as conforming to the respective industry EMC regulations.		N/A
	A road ambulance as supplied and certified may not be fully equipped and therefore some responsibility for added equipment after conversion rests with the customer/user.		N/A
<b>4.2.3</b>	<b>Battery and alternator</b>		N/A
	Batteries shall be positioned to allow maintenance without removing the battery from its securing device. The construction of the battery and all connections to it shall be such as to prevent any possibility of an inadvertent short circuit.		N/A



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EN 1789:2020			
Clause	Requirement	Remarks	Verdict
	For types A2, B and C road ambulances the electrical system shall be capable of holding a reserve of electrical power for restarting the engine. The characteristics of the alternator, the starter batteries as well as additional batteries, if fitted, shall comply with Table 1.		N/A
	Additional batteries may be required to power the medical devices carried on board and the intended use of the road ambulance.		N/A
	When the engine is idling electrical stability should be maintained between electrical load and alternator output. In order to achieve this it may be necessary to fit an electrical load prioritization device to the vehicle.		N/A
<b>4.2.4</b>	<b>Electrical installation</b>		N/A
<b>4.2.4.1</b>	In type B and C road ambulances there shall be a recessed externally mounted power connector to enable external power to be provided for operations such as the following: — charging battery(ies); — operating medical devices, when installed; — operating a patient compartment heater, when installed; — operating an engine preheater, when installed.		N/A
	The connector for 110 V or 220/240 V shall be a male connector and not interfere with the electrical and mechanical safety.		N/A
	It shall not be possible to start the engine whilst it is connected to an external power supply unless an automatic mechanical disconnection is fitted.		N/A
	If no automatic mechanical disconnection is fitted, the connector shall be on the driver's side.		N/A
	The 110 V or 220/240 V circuit shall be protected either by an "earth leakage device" with a maximum setting of 30 mA or by a separate transformer. If the protection is given only by an "earth leakage device" there shall be a label near the plug that reads as follows: "CAUTION! CONNECT ONLY TO AN AUTHORISED SOCKET."		N/A



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EN 1789:2020			
Clause	Requirement	Remarks	Verdict
4.2.4.2	A minimum number of separately protected 12 V DC outlets shall be available according to Table 2. The outlets shall be available for medical devices, located in the area of use and in the storage area. The nominal voltage shall be 13,8 V. Voltage fluctuations shall not exceed the range of 12,4 V and 15,1 V.		N/A
	The power supply shall continuously supply the medical devices with electrical power with the engine running. The outlets for the medical devices shall be labelled with the nominal voltage and current rating. The outlets shall have a visible indication under intended operational conditions in order to show if there is voltage on the outlet.		N/A
	If the road ambulance is intended to carry a transport incubator system it shall have a four-pole connector as specified in EN 13976-1:2018, subclause 4.2.3, Figure 2. In that case the nominal current needs to be assessed (minimum 23 Amp according to EN 13976-1:2018, subclause 4.1.3).		N/A
4.2.4.3	Any additional electrical systems fitted to the base vehicle shall be separate from the base vehicle electrical system and the body or chassis shall not be used as an earth return for additional circuits.		N/A
	All circuits in the additional system(s) shall have separate overload protection. All circuits shall be well identified and cables clearly marked at the connection points and at a maximum of 1 m intervals along its length.		N/A
	The system shall have enough circuits and be so constructed that when/if a circuit fails the patient treatment area shall remain illuminated and at least one power supply source for medical technical equipment shall still work.		N/A
	Every power socket in the patient compartment shall be fitted with a permanently visible indicator light to confirm that there is power to the socket.		N/A
4.2.4.4	No wiring shall be located in or pass through conduit intended for medical gas installation. The wiring shall not be loaded higher than that stated by the wire manufacturer.		N/A
4.2.4.5	Where there are different voltage systems, the connections shall be non-interchangeable.		N/A



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EN 1789:2020			
Clause	Requirement	Remarks	Verdict
4.2.5	<b>Visual warning system and audible warning system (siren)</b>		N/A
4.2.5.1	<b>General</b>		N/A
	The road ambulance shall be fitted with a visual warning and audible warning system (in accordance with national regulations) to alert other road vehicles and pedestrians of its approach, in order to expedite its journey through traffic, whilst being used for emergency operation.		N/A
4.2.5.2	<b>Visual warning system</b>		N/A
	The vehicle shall have 360-degree visibility of warning lights around the vehicle.		N/A
	Recommended additional warning lights for type B and type C road ambulances are: — additional warning lights facing forward, sideways of the vehicle (front and rear corner) and facing backwards to ensure traffic safety and high visibility in heavy traffic.		N/A
4.2.5.3	<b>Audible warning systems (siren)</b>		N/A
	The vehicle shall have an audible warning system additional to the warning lights. The audible warning system shall activate the visual warning light.		N/A
	The audible alarm can only be in function if the visible alarm is in operation.		N/A
4.2.6	<b>Reversing systems</b>		N/A
	The ambulance shall be fitted with an audible reversing warning alarm, activated by the selection of the reverse gear. This function shall be possible to disable from the driver seating position, with default back to on, when reverse gear is engaged the next time.		N/A
	There shall be a system enabling the driver to detect obstacles behind.		N/A
4.2.7	<b>Exterior illumination lights</b>		N/A
	Exterior lighting with a minimum of 5 lx illuminating the surrounding the patient compartment area according to Figure 1 shall be provided on type B and type C vehicles. Illumination shall be measured at ground level.		N/A
4.3	<b>Vehicle body</b>		--



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EN 1789:2020			
Clause	Requirement	Remarks	Verdict
<b>4.3.1</b>	<b>Fire safety</b>	Not road ambulance	N/A
	All interior materials shall have a burning rate of less than 100 mm/minute when tested in accordance with ISO 3795:1989.		N/A
<b>4.3.2</b>	<b>Driver's seat configuration</b>		N/A
	For all types of road ambulances the ergonomic space of the driver's compartment and of the seat adjustment as approved by the base manufacturer shall not be reduced.		N/A
<b>4.3.3</b>	<b>Minimum passenger capacity</b>		N/A
	The minimum passenger capacity shall be in accordance with Table 3.		N/A
	A notice shall be displayed in the drivers' compartment stating the maximum number of seated and stretcher passengers that can be carried.		N/A
	The notice shall be supplied by the manufacturer taking into account the maximum weight capacity of the vehicle.		N/A
<b>4.3.4</b>	<b>Bulkhead</b>		N/A
	A full bulkhead or a bulkhead with a door shall separate the driver's compartment from the patient's compartment. Where a door is fitted, it shall not be possible to drive the vehicle with the door in the open position. This door shall be secured against opening if the road ambulance is in motion.		N/A
	One or two windows with a minimum separation of 100 mm shall be provided in the bulkhead. The windows shall allow direct visual contact with the driver. The opening area of the window shall have a maximum area of 0,2 m2. It shall be secured against self-opening and shall have an adjustable blind or other means of preventing the driver being disturbed by the light of the patient's compartment.		N/A
<b>4.3.5</b>	<b>Openings (doors, windows, emergency exits)</b>		N/A



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EN 1789:2020			
Clause	Requirement	Remarks	Verdict
	<p><b>4.3.5.1 General</b>                      The patient compartment shall have at least two openings. One at the rear (door/tailgate) and one at the side.                      All openings shall have seals to protect against the ingress of water.                      All openings shall comply with the minimum dimensions according to Table 4.</p>		N/A
	<p><b>4.3.5.2 Emergency exits</b>                      The patient compartment shall have at least two emergency exits on different sides of the vehicle. One of the emergency exits can be on the roof. The emergency exits shall be easy to open from the inside.                      The side door and rear door can be used as emergency exits. The free minimum size shall be 500 mm x 700 mm.</p>		N/A
	<p><b>4.3.5.3 Doors</b>                      There shall be a central locking system which shall be possible to operate from the driver and patient compartment.                      Each external door allowing direct access to the patient's compartment shall be fitted with a security system which enables the following:                      a) lock and unlock from inside without use of a key;                      b) lock and unlock from outside with use of a key;                      c) unlock from the outside using a key when the door is locked from the inside;                      The patient's compartment doors shall be capable of being positively restrained in the open position.                      An audible and/or visual signal shall warn the driver when any external door including those not allowing direct access to the patient's compartment, is not completely closed when the vehicle is in motion.                      Handles and/or handrails of all access points shall be accessible from the outside.</p>		N/A



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EN 1789:2020			
Clause	Requirement	Remarks	Verdict
	<p><b>4.3.5.4 Windows</b></p> <p>In the patient's compartment, there shall be a minimum of two external windows. There shall be one on each side or one on one side and the rear.</p> <p>The windows shall be positioned or designed to ensure patient's privacy when required.</p>		N/A
<b>4.3.6</b>	<b>Loading area</b>		N/A
	The loading area dimensions shall be in accordance with Table 5.		N/A
	Where a ramp or lift is installed between ground level and vehicle floor level it shall be covered with an anti-slip surface and capable of taking a load of 350 kg. In the event of a power failure the loading device shall be capable of being operated manually.		N/A
<b>4.4</b>	<b>Patient's compartment</b>		--
<b>4.4.1</b>	<b>General</b>		N/A
	The patient's compartment shall be designed and constructed to accommodate the medical devices listed in Tables 9 to 19 in accordance with the road ambulance type.	Not road ambulance	N/A
<b>4.4.2</b>	<b>Safety</b>	Not road ambulance	N/A
	Exposed edges that could come into contact with the occupant's hands, legs, head etc., during normal use shall have a radius of curvature of not less than 2,5 mm except in the case of projections of less than 3,2 mm. In this case, the minimum radius of curvature shall not apply provided the height of the projection is not more than half its width and its edges are blunted.		N/A
	All installations in the patient compartment above 700 mm shall not have sharp exposed edges and shall terminate in rounded edges. A sharp exposed edge is defined as an edge of a rigid material having a radius of curvature of less than 2,5 mm.		N/A



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EN 1789:2020			
Clause	Requirement	Remarks	Verdict
	Edges that can be contacted by using the apparatus and procedure described in 5.4 shall have an edge with radius of curvature greater than or equal to 2,5 mm or shall be made from a non-rigid material. Medical equipment and their holding devices (for example stretchers, platforms, suction units etc.) are excluded.		N/A
	Edges on medical equipment and their holding devices should be designed to reduce the risk of contact injury.		N/A
	Cabinet drawers and doors shall be secured against self-opening and where lockers are fitted with doors that open upwards they shall be fitted with a positive hold open mechanism. Type B and C road ambulances shall be equipped with a lockable drugs compartment with security lock.		N/A
	Floor coverings shall provide adequate grip including when wet and should be durable and easy to clean.		N/A
	They shall as a minimum have achieved a slip resistance grading of at least R10 according to DIN 51130:2014 using testing method as defined in CEN/TS 16165:2016.		N/A
	Type B and C road ambulances shall be fitted with a hand-holding device positioned above the stretcher. For type C the hand-holding device shall be positioned along the longitudinal axis.		N/A
	If the patient's compartment is to be equipped with a non-foldable sedan chair as defined in EN 1865-1:2010+A1:2015, space shall be provided with a width of at least 600 mm measured at elbow height and a ceiling height above the seat squab of at least 920 mm (see Table 7, footnote a).		N/A
	Vehicle maintenance equipment (e.g. spare wheel and tools) shall not be accessible from within the patient's compartment. Devices, equipment and controls which may be required while the vehicle is in motion should be positioned in such a way that they can be operated with the seat belt fastened while the vehicle is in motion.		N/A
<b>4.4.3</b>	<b>Hygiene</b>	Not road ambulance	N/A



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Clause	Requirement	Remarks	Verdict
	To provide a safe environment and maintain hygiene standards for both patients and crew, the equipment and interior design of an ambulance should allow for ease of cleaning to provide for infection control and prevent cross contamination. The interior of the patient compartment including the ceiling, floor, walls and doors shall be lined with a material that is non-permeable and resistant to continuous cleaning.		N/A
	The edges of all surfaces shall be designed and/or sealed in such a way that no fluid can infiltrate. If the floor arrangement does not allow fluids to flow away, one or more drain with plugs shall be provided.		N/A
	For further information see the informative Annex C.		N/A
<b>4.4.4</b>	<b>Patient's compartment dimensions</b>	Not road ambulance	N/A
	<b>4.4.4.1 General</b> The dimensions relate to the patient's compartment with lining. To achieve only structural solidity a reduction of the dimensions of up to 5 % is acceptable in limited areas; door openings excluded.		N/A
	<b>4.4.4.2 Patient's compartment dimensions for type A1, A2 and B road ambulances</b> The patient's compartment shall comply with the minimum dimensions set out in Figures 3 to 5 (without cupboards, seats, medical devices and equipment). For the Figures 3 to 5 the following key applies: <i>W</i> = width measured from from side wall to side wall, except the roof curvature; <i>L</i> = length measured from rear to bulkhead at height of stretcher; <i>H</i> = height, measured from floor to roof; <i>X</i> = height of stretcher holding assembly to roof measured in the middle of the longitudinal axis of the stretcher; <i>h1</i> = height between centre of seat and roof; <i>h2</i> = height between centre of seat and floor.		N/A



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Clause	Requirement	Remarks	Verdict
	<p><b>4.4.4.3 Patient's compartment and treatment area dimensions for type C</b></p> <p>In type C road ambulances the patient's compartment shall be large enough to incorporate the treatment area provided with dimensions as set out in Figure 6. Any protrusions into the treatment area shall be designed and constructed to fold away to provide these minimum dimensions. A seat (in stored position) and the medical equipment operated from this seat may intrude into the treatment area as follows:</p> <ul style="list-style-type: none"> <li>— in this case the maximum intrusion shall be 125 mm at the head end of the stretcher;</li> <li>— or 125 mm on one side or a sum of 125 mm on both sides.</li> </ul> <p>Verification of conformity of dimension of the treatment area shall be made when the stretcher is placed in the mean position of the treatment area.</p> <p><math>h</math> = A working height of the stretcher surface (excluding mattress and included a support platform where fitted) between 320 mm (minimum) and 650 mm (maximum) shall be ensured; measured at the head end of the stretcher.</p> <p><math>R</math> = 500 mm (maximum), where <math>R</math> is the radius.</p>		N/A
<b>4.4.5</b>	<b>Patient and crew seating</b>	Not road ambulance	N/A
	The minimum number of patient and crew seats shall be as given in Table 6.		N/A
	The seats shall comply with the minimum dimensions according to Table 7.		N/A
	Where possible the seat height should be adjustable.		N/A
	Seats fitted in accordance with Tables 6 and 7 shall be installed in either forward or rear-facing positions. Backrests shall be constructed to a minimum dimension of 300 mm x 100 mm, the upholstery of which shall be a minimum thickness of 20 mm.		N/A
	All seats shall be equipped with head rests.		N/A



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Clause	Requirement	Remarks	Verdict
	Seats in the patient compartment shall be fitted with a seatbelt alarm. The seatbelt alarm shall alert the driver visually or acoustically when someone is seated but not secured by the seatbelt.		N/A
<b>4.4.6</b>	<b>Ventilation and anaesthetic gas scavenging systems</b>	Not road ambulance	N/A
	<b>4.4.6.1 Ventilation system</b> There shall be a ventilation system which shall provide a minimum of 20 air changes per hour when the vehicle is stationary.  For safety, if a pressurized gas is stored in a storage compartment, the compartment shall be ventilated.		N/A
	<b>4.4.6.2 Anaesthetic gas scavenging system (AGSS)</b> If the ambulance is intended to be used with delivery systems for anaesthetic gases e.g. N2O or anaesthetic agent vapour it shall be equipped with an AGSS to make sure that the maximum permissible level of air contamination is not exceeded. This level is found in national or regional regulations.		N/A
<b>4.4.7</b>	<b>Temperature control system</b>	Not road ambulance	N/A
	<b>4.4.7.1 General</b> Heating and cooling systems in the patient compartment shall be independently controlled from the driver's compartment system. Heating/cooling in the patient compartment can be provided in a combined system.		N/A



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Clause	Requirement	Remarks	Verdict
	<p><b>4.4.7.2 Heating</b></p> <p>In addition to the heating of the driver's compartment there shall be an independent adjustable system as follows:</p> <ul style="list-style-type: none"> <li>— heating for type A and B road ambulance;</li> <li>— fresh air heating for type C road ambulances.</li> </ul> <p>This system shall be such that given an outside and inside temperature of 5 °C, the heating up to at least 22 °C shall not take longer than 15 min when measured in the centre of the stretcher(s) and at the midpoint from the heater outlets (if several outlets are available).</p> <p>The heating shall be controlled by an adjustable thermostat or by an electronic climate control system.</p> <p>The actual temperature shall not vary from the set temperature by more than 5 °C.</p> <p>The heating system shall be capable of meeting the performance criteria with the ventilation system switched off and the heating system set to re-circulate the air in the patient's compartment.</p> <p>The installation of the system shall not encourage exhaust gases entering the patient's compartment.</p>		N/A
	<p><b>4.4.7.3 Cooling</b></p> <p>At an inside temperature of 32 °C, the cooling system shall reduce the temperature in the patient's compartment to 27 °C or less within 15 min and reduce to 25 °C or less within 30 min.</p> <p>The temperature shall be measured in the centre of the stretcher(s) and at the midpoint from the cooling outlets (if several outlets are available).</p> <p>The cooling system shall be able to meet the requirements if the air conditioning system is set to the air recirculation of the patient compartment.</p> <p>The installation of the system shall not encourage exhaust gases entering the patient's compartment.</p>		N/A
<b>4.4.8</b>	<b>Interior lighting</b>	Not road ambulance	N/A



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Clause	Requirement	Remarks	Verdict
	Natural colour balance lighting shall be provided as set out in Table 8. In type C road ambulances there shall be an additional light within the treatment area with a minimum of 1 650 lx. It shall be measured at the stretcher surface in its lowest position. The minimum distance of the measurement shall be 750 mm below the light and in an area with a minimum diameter of 200 mm.		N/A
	Light levels shall be measured along the central longitudinal axis of the stretcher at the head, mid-point and foot position with the stretcher in its normal position for transportation in the ambulance.		N/A
<b>4.4.9</b>	<b>Interior noise level</b>	Not road ambulance	N/A
	The noise level in the patient and drivers compartment shall be kept as low as possible across the vehicle speed range. Maximum sound pressure level shall not exceed 77 dB(A) at 120 km/h or the vehicle maximum speed if it is lower than 120 km/h.		N/A
	Noise measurements shall be made using the most appropriate gear for the speed being examined as determine by the base vehicle manufacturer.		N/A
<b>4.4.10</b>	<b>Holding system for infusion</b>	Not road ambulance	N/A
	A holding system shall be provided to support two vertically fixed infusions in such a way as to use the maximum available height above the stretcher holding assembly. It shall be possible to position the infusions for use at either end of the stretcher holding assembly. The infusion mounting shall have a minimum capacity of 5 kg and be able to hold two bags of fluids independent of each other and shall be designed to minimize oscillation.		N/A
<b>4.4.11</b>	<b>Retention, fixation and restraint systems</b>		P



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Clause	Requirement	Remarks	Verdict
	All persons and items e.g. medical devices, equipment and objects carried in the road ambulance shall be restrained, installed or stowed to prevent them becoming a projectile when subjected to accelerations/decelerations of 10 g in the forward, rearward, left, right and vertical directions. When subjected to these accelerations/decelerations, the distance travelled by a person or item shall not endanger the safety of persons in the road ambulance.	For medical device used in road ambulance: Using the static test method (refer to attachment 1) provided by applicant, which was not evaluated in this report Tested equipment with specified fixation holder	P
	After being subjected to these accelerations/decelerations: a) no items shall have sharp edges or endanger the safety of persons in the road ambulance; b) the maximum distance the stretcher and any item attached to either the holding assembly or stretcher may travel shall be no more than 150 mm. The displacement of the patient during the test may exceed 150 mm.	No damage or hazardous situation occurred	P
	All lockers, rails and non-dedicated storage locations or storage devices shall be labelled to show the total maximum permissible weight allowed.		N/A
	If the road ambulance is intended to carry a transport incubator system and the incubator is to be interchangeable between road ambulances and other vehicles or craft, then to ensure interoperability and interchangeability an interface as specified in EN 13976-1:2018, Clause 4.1 shall be used.		N/A
<b>4.4.12</b>	<b>Mass reserve</b>	Not road ambulance	N/A
	The minimum mass reserve required for the listed sanitary, medical and technical devices in Tables 9 to 19 shall be as follows: — road ambulance type A1: 100 kg; — road ambulance type A2: 115 kg; — road ambulance type B: 225 kg; — road ambulance type C: 260 kg.		N/A
<b>5</b>	<b>Testing</b>		--
<b>5.1</b>	<b>General</b>		P
	Equipment in the road ambulance shall be in place during testing according to 5.2 and 5.3.	For testing of 5.3	P



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Clause	Requirement	Remarks	Verdict
	Stretcher(s) shall be loaded according to this standard and be tested in the normal position for use.	Not road ambulance	N/A
<b>5.2</b>	<b>Testing of the interior noise level</b>		--
<b>5.2.1</b>	<b>Specific measurement conditions</b>	Not road ambulance	N/A
	<p>The measurements of the interior noise level in the patient's compartment shall be taken under the conditions given in ISO 5128:1980 with the following exceptions:</p> <ul style="list-style-type: none"> <li>— the road ambulance shall be provided with the permanently installed equipment specified in this document;</li> <li>— contrary to the minimum tyre wear of 300 km specified in ISO 5128:1980, 8.1, new tyres without wear may be used;</li> <li>— apart from the requirements in ISO 5128:1980, 8.3, the stretcher trays shall be in the normal position according to the manufacturer's recommendations;</li> <li>— the measurement shall be made at a constant speed in accordance with ISO 5128:1980, 8.4.1 b);</li> <li>— the measurements in accordance with ISO 5128:1980, 8.4.2 and 8.4.3, are not necessary;</li> <li>— measurements shall only be taken in the patient's compartment and are required on all seats of the patient's compartment (including lying/carrying chair) according to ISO 5128:1980, 9.1, (but only in the longitudinal median plane of the seat) and on all stretchers according to ISO 5128:1980, 9.3;</li> <li>— determination of octave and terz spectrums, according to ISO 5128:1980, 10.6, is not necessary;</li> <li>— during the measurements, the audible warning and communication system shall be switched off.</li> </ul>		N/A
<b>5.2.2</b>	<b>Measurements</b>	Not road ambulance	N/A
	The noise level of the vehicle at the speed according to 4.4.9 is determined by measuring the interior noise level in the patient's compartment at a speed of 120 km/h, or at the vehicle maximum speed if it is lower than 120 km/h		N/A



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Clause	Requirement	Remarks	Verdict
	Two measurements are carried out. The test result is the average of these two measurements.		N/A
<b>5.3</b>	<b>Testing of retention systems and fixation of the equipment in the patient's compartment</b>		--
<b>5.3.1</b>	<b>General</b>		P
	The requirements of 4.4.11 should be verified by a third party.		P
	For verification of the requirements of 4.4.11 a dynamic test under 5 axis, $\pm x/x$ , $\pm y/y$ and for $+z/z$ axis shall be performed (see Figure 7).	For medical device used in road ambulance Using the static test method (refer to attachment 1) provided by applicant, which was not evaluated in this report	P
	The test body or shell is determined depending on the ambulance construction: — For a panelled van, the body shell of the base vehicle shall be used. — A box body requiring structural support of the base chassis shall be tested jointly. — A box body not requiring structural support of the base chassis is tested without base chassis, or on request of the manufacturer, with the base chassis.		N/A
	It is permissible to perform the test in each direction on a fresh sample body at the request of the manufacturer.		N/A
	Each direction in the test is an independent test. Use of fresh sample body is therefore allowed.		N/A
	If the patient's compartment or base chassis is changed in a way that it cannot be covered by the original worst case scenario, a full or partial test shall be performed as deemed necessary.		N/A
	Test configuration is defined on the principle of the worst-case scenario to limit the number of tests. The test sample does not have to be the actual product rather than as worst case scenario.		N/A
	The maximum test mass for which the devices are qualified shall be indicated by a label.		N/A



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Clause	Requirement	Remarks	Verdict
	The method used to secure the vehicle during the test shall not be such as to strengthen the body or the arrangement of the patient's compartment or to lessen the normal deformation of the structure.		N/A
	The only reinforcements allowed are: — a sub frame under the original van shell; or — chassis longitudinal box sections; or — chassis rails to fix the body/shell to the test facility.		N/A
	For a box body, a sub frame representing the chassis can be used in conjunction with the original attachment points under the box designated for fixing to the vehicle chassis.		N/A
	In the case of a fully independent box body, it is possible to test it alone.		N/A
	To check 4.4.11 on a new vehicle, a dynamic test in the five directions shall be carried out. Dynamic test is the reference method.		N/A
	Manufacturer shall present documentation of the fixation and retention system.		N/A
	For a modification on a previously dynamically tested and approved ambulance body or shell, a dynamic test or a static test of the modified components or a computer simulation can be presented depending on the nature of the change. The appropriate method shall be agreed with the approval authority.	Using the static test method (refer to attachment 1) provided by applicant	P
	Documentation of all modifications shall be added to the original tests documentation.		N/A
	For racks, rails and non-dedicated storage devices or storage, the test report shall state the maximum approved load. The test mass shall remain fixed to the attachment point. Cracks and tears of metal sheet are acceptable.	After test, the medical device was retained on the fixation holder. No cracks or tears of metal sheet	P
<b>5.3.2</b>	<b>Testing of the stretcher fixation on the vehicle floor</b>	Not stretcher	N/A



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Clause	Requirement	Remarks	Verdict
	For all types, the test shall be performed with a stretcher support or floor mounted locks and an equivalent mass simulating the stretcher and the dummy whose characteristics are: — stretcher and dummy test mass: 126 kg according to EN 1865-5:2012; — table stretcher support as defined by the ambulance manufacturer, with maximum weight and height of the centre of gravity defined by the ambulance manufacturer.		N/A
	Manufacturer shall present documentation of the fixation and retention system. In addition, the stretcher support fixed in the ambulance shall comply to EN 1865-5:2012.		N/A
<b>5.3.3</b>	<b>Testing of the medical devices fixation</b>	Not road ambulance	N/A
	Fixation points shall be tested with a test mass corresponding to the permissible load declared by the manufacturer of the ambulance for each point.		N/A
<b>5.3.4</b>	<b>Testing of furniture</b>	Not road ambulance	N/A
	For the same vehicle type or a specific box body, the patient's compartment furniture shall be validated utilizing the worst case condition.		N/A
	The test is carried out according to 5.3.5. The test shall be performed with simulation mass easily removable from the furniture without tools.		N/A
	The maximum allowed load, expressed in kg, shall be visible to the users.		N/A
<b>5.3.5</b>	<b>Test procedure</b>		P
	For test purposes a surrogate stretcher can be used and shall be fixed to its locking devices in the same way as the original product, and surrogate masses representing medical devices can be used.		N/A
	Verification of conformity to 4.4.11 shall be made when the stretcher(s)/medical device(s) is/are placed in the mean position of all possible positions available.		P
	Appropriate verification shall be carried out by static or dynamic testing depending on the individual technical problem.		P



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Clause	Requirement	Remarks	Verdict
	The sample submitted for test shall be identical to or have the same characteristics and behaviour during test as the production item or vehicle.		P
	Care should be taken that no internal/external additional reinforcement through the rig modifies the behaviour during the test.		P
	The surrogate of the stretcher shall be fixed on the stretcher's holding assembly. The non-foldable carrying chair, when provided, shall also be fixed in its holder. Representative test mass can be used.		N/A
	The impact tests can be carried out with medical device(s) installed or stowed in the holding system(s) or with weights having the mass distribution and dimensions corresponding to the mass and dimensions of the stretcher(s) and device(s) intended to be installed on or stowed in the holding system.	Using the static test method (refer to attachment 1) provided by applicant	P
	In case of dynamic testing, the dynamic test shall be carried out using a patient's compartment assembly and the following test method. When a modification to an approved ambulance patient's compartment requires testing, a relevant part of the construction may be used		N/A
	The test assembly shall be accelerated/decelerated in the longitudinal, transverse and vertical directions in accordance with Figure 8. The impact speed shall be between 30 km/h and 32 km/h.		N/A
	The deceleration curve is verified according to the inertia mass method.		N/A
	Test weights for use in lockers should be sand bags with masses in kg increments, with a tolerance of 0 % to +10 % maximum of the maximum of each individual compartment load.		N/A
<b>5.4</b>	<b>Testing of rounded edges and radius inside the patient's compartment</b>		--
<b>5.4.1</b>	<b>Testing of rounded edges</b>	Not road ambulance	N/A
	Conduct the test with a protrusion test ball shown in Figure 9 having a diameter of 165 mm.		N/A



EN 1789:2020			
Clause	Requirement	Remarks	Verdict
	All doors in the patient's compartment and drawers shall be in closed position. Manoeuvre the protrusion test ball in all possible attitudes towards any rigid protrusion on the furniture above the plan. The plan is the horizontal plan located at 700 mm from the lowest point of the floor excluding steps or wells.		N/A
	If the protrusion test ball contacts the protrusion (see Figure 10), that protrusion shall be considered to be an exposed edge and shall comply with 4.4.2.		N/A
<b>5.4.2</b>	<b>Testing of radius inside the patient's compartment</b>	Not road ambulance	N/A
	Conduct the test with a radius test tool shown in Figure 11.		N/A
<b>5.5</b>	<b>Procedure to verify the patient's compartment specifications</b>	Not road ambulance	--
	Vehicle converter shall provide the technical specification of the flooring material and confirmation of anti-slip properties.		N/A
	The manufacturer shall demonstrate that surface joints of the floor, ceiling, walls and doors are designed and/or sealed in such a way that no fluid can infiltrate.		N/A
<b>5.6</b>	<b>Procedure to verify the loading area specifications</b>	Not road ambulance	--
<b>5.6.1</b>	<b>General</b>		N/A
	The presented vehicle shall be equipped with a stretcher complying to EN 1865-1:2010+A1:2015 or EN 1865-2:2010+A1:2015 provided by the ambulance manufacturer and when appropriate with its stretcher support. The test shall be conducted on a flat and horizontal surface.		N/A
<b>5.6.2</b>	<b>Procedure to verify the loading angle of 16°</b>	Not road ambulance	N/A
	For verification of the loading angle see Figure 12.		N/A
	Check the loading angle and loading height with one of the stretcher specified by the manufacturer of the ambulance.		N/A



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EN 1789:2020			
Clause	Requirement	Remarks	Verdict
	If the vehicle is fitted with lowering rear suspension, it should be fully lowered. Where it is fitted, the vehicle shall be tested with a mass of 150 kg within the patient's compartment in addition to the stretcher and its locks, mountings and loading platform where appropriate.		N/A
	Where a loading ramp is provided this should be fully deployed.		N/A
	For vehicles equipped with a stretcher support (lift table), position it in the loading position according to the instructions for use. In the absence of instructions, the top tray shall be positioned such that the surface to its rear end on which the attack wheels of the stretcher engage are at the same height as the tread of the stretcher attack wheels (or the top of the undercarriage if so equipped).		N/A
	Loading angle $\alpha$ is measured as being the incline of the ramp from ground to vehicle floor or slope of the loading platform where used.		N/A
	If a ramp is fitted to the vehicle: — verify the presence of non-slip coating on the vehicle; — Verify the strength of the ramp by placing it in a horizontal position and by placing a load of 350 kg uniformly distributed over an area of 200 mm x 200 mm at the centre of the ramp (see Figure 13) for 60 s. Support shall be placed at 300 mm of each end. After removing the load, no deformation is permitted.		N/A
	Check dimension $H_2$ , with the suspension of the vehicle in same position as that recommended to check the loading angle $\alpha$ .		N/A
<b>5.7</b>	<b>Procedure to verify the dimensions of the patient's compartment</b>		--
<b>5.7.1</b>	<b>Type A and B road ambulances</b>	Not road ambulance	N/A
	Dimensions shall be checked in an ambulance fully fitted with all interior, sides and ceiling lining panels. Other interior fittings and medical devices (with the exception of the stretcher, loading platform where used and permanent seats) are to be ignored for this test.		N/A
<b>5.7.2</b>	<b>Type C road ambulances</b>		N/A



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EN 1789:2020			
Clause	Requirement	Remarks	Verdict
	The dimensions of the patient's compartment are checked without medical devices fitted.		N/A
	To check the dimensions of the ergonomic space in the vehicle, use a main stretcher to the nominal dimensions of EN 1865-1:2010+A1:2015 in the position corresponding to the main settings as defined by the ambulance manufacturer.		N/A
	Dimensions are checked on the stretcher lying surface excluding the mattress.		N/A
	If the dimensions of the stretcher support are higher than those of the stretcher, check the ergonomic space dimensions around the stretcher support.		N/A
	Ergonomic space is checked at the level of the horizontal plan tangent to the top tray of the stretcher support.		N/A
	Consider the possible authorized maximum intrusion at the head end of the stretcher or on one side (see 4.4.4.3).		N/A
	Oxygen cylinders, which can be operated from a seat and the flexible part of their support, can enter the ergonomic space under the conditions of 4.4.4.3.		N/A
	The intrusion of seats is checked in the stretcher plan.		N/A
<b>5.8</b>	<b>Procedure to verify the seats dimensions of the patient's compartment</b>		--
	Check the dimensions of the seats in Table 7 as shown in Figure 14. The dimensions of the seats shall be checked physically or by reference to drawings. Rounded corners are to be ignored.	Not road ambulance	N/A
	The width of the carrying chair at the elbow level, including width of the chair, shall be measured at a height between 250 mm to 300 mm above the seat (conventional elbow height).		N/A
	Check that swivel seats can be locked, in predetermined position, front or rear facing.		N/A
	Seats not intended for use when the vehicle is travelling are not included in this section. They are not necessarily equipped with seat belt and headrest.		N/A



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EN 1789:2020			
Clause	Requirement	Remarks	Verdict
	In the event that the seat's design implies a reduction of the seat at the height of H point due to rotating axis allow a significant reduction in the width at -30 mm of H point (dotted line on Figure 15).		N/A
	Seats designed with tip up seat bases may have the 450 mm width dimension reduced adjacent to the back rest. See dotted area in Figure 15.		N/A
	Ensure that the dimension of the seat is not less than a 300 mm by 450 mm rectangle taken 30 mm from H point.		N/A
<b>5.9</b>	<b>Testing of the ventilation system</b>		--
	It shall be verified by: — checking the technical documentation of the product; — checking the calculation that the choice of the product allows at least 20 changes per hour of the air volume of the patient's compartment (without interior arrangement).	Not road ambulance	N/A
<b>5.10</b>	<b>Testing of the heating system</b>		--
	This procedure shall be used for all types of ambulance (A, B, C).	Not road ambulance	N/A
	There shall be no external power supply connected.		N/A
	If necessary install a coolant temperature sensor at the T connection of the heater (engine side).		N/A
	a) open the doors of the patient's compartment; b) condition the vehicle for at least 6 h at the temperature specified in 4.4.7.1; c) check that the patient's compartment heating system is turned off; d) start the engine; e) start the heater of the driver's compartment in the most favourable position; f) operate the engine until it reaches its normal operating temperature (the engine is considered hot after two openings of the thermostat); g) close the doors of the patient's compartment, start the heating system of the patient's compartment (control in maximum position), with the engine at idle speed or accelerated idle speed if it comes into operation during the test without manual action.		N/A



EN 1789:2020			
Clause	Requirement	Remarks	Verdict
	The test report shall indicate if the accelerated idle came into action during the test.		N/A
	Start of test: t0 — record the temperature over time. End of the test: t0 + 20 min — Validation of the test: the temperature sensors shall reach the values indicated in 4.4.7.1 at t0 + 15 min.		N/A
	The measurements recorded on one sensor at the centre of the stretcher shall meet the criteria.		N/A
	Given the varying conditions of use of ambulances, check the set temperature only by comparing the displayed temperature (22°C) after 15 min temperature rise. The measured temperature shall not differ by more than 5°C.		N/A
<b>5.11</b>	<b>Testing of the cooling system</b>		--
<b>5.11.1</b>	<b>Test procedure</b>	Not road ambulance	N/A
	a) open the doors of the patient's compartment; b) condition the vehicle for at least 6 h at the temperature specified in 4.4.7.2; c) start the engine; d) start the air conditioning of the driver's compartment; e) wait for 10 min; f) close the doors of the patient's compartment, start the air conditioning system of the patient's compartment (control in maximum position), with the engine at idle speed or accelerated idle speed if it comes into operation during the test without manual action.		N/A
	Start of test: t0 — record the temperature over time. End of the test: t0 + 35 min — Validation of the test: the temperature sensors shall reach the values indicated in 4.4.7.2 at t0 + 15 min and t0 + 30 min.		N/A
<b>5.11.2</b>	<b>Testing of independent air conditioning system</b>	Not road ambulance	N/A



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EN 1789:2020			
Clause	Requirement	Remarks	Verdict
	a) open the doors of the patient's compartment; b) condition the vehicle for at least 6 h at the temperature specified in 4.4.7.2; c) close the doors of the patient's compartment, start the air conditioning system of the patient's compartment (control in maximum position). Start of test: t0 — record the temperature over time. End of the test: t0 + 35 min — Validation of the test: the temperature sensors shall reach the values indicated in 4.4.7.2 at t0 + 15 min and t0 + 30 min.		N/A
	The measurements recorded on one sensor at the centre of the stretcher shall meet the criteria.		N/A
	Given the varying conditions of use of ambulances, check the set temperature only by comparing the displayed temperature (22°C) after 30 min temperature rise. The measured temperature shall not differ by more than 5 °C.		N/A
<b>5.12</b>	<b>Testing of interior lighting</b>		--
	The test shall be performed in a darkroom or with the exterior surface of all saloon windows covered in non-light transmitting material to avoid light entering.	Not road ambulance	N/A
	For types B and C ambulances take the lowest possible position of the stretcher into account.		N/A
	The measurements shall be taken with the mattress in place.		N/A
	Before starting the measurement wait a minimum of 10 min after switching the light on.		N/A
<b>5.13</b>	<b>Testing of infusion holding system</b>		--
	Each infusion holding system shall be loaded with a mass of 5 kg for a dynamic test and 7,5 kg for a static test. In the case of an adjustable/mobile holder, position the mass in the longitudinal axle of the stretcher at the middle.	Not road ambulance	N/A
<b>6</b>	<b>Equipment and medical devices</b>		--
<b>6.1</b>	<b>Provision of medical devices</b>		--



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EN 1789:2020			
Clause	Requirement	Remarks	Verdict
	The road ambulance shall be designed and constructed to accommodate the items listed in Tables 9 to 19 and provide the following levels of care: — the patient transport ambulance (types A1 and A2) shall have basic professional equipment for first aid and nursing care; — the emergency ambulance (type B) shall have equipment for basic treatment and monitoring of patients with the current methods of pre-hospital care; — the mobile intensive care unit (type C) shall have equipment for advanced treatment and monitoring of patients with the current methods of pre-hospital intensive care.	Not road ambulance	N/A
<b>6.2</b>	<b>Medical devices storage</b>		--
	All equipment required for a set procedure shall be stowed in a specified location. Essential equipment required for use outside the vehicle shall be easily accessible via normally used doors. All equipment shall be securely and safely stowed to prevent damage or injury whilst the vehicle is in motion (see 6.3.5). Devices, equipment and controls which may be required while the vehicle is in motion should be positioned in such a way that they can be operated with the seat belt fastened while the vehicle is in motion.		N/A
<b>6.3</b>	<b>Requirements for medical devices</b>		--
<b>6.3.1</b>	<b>General</b>		P
	For all electrical and non electrical medical devices the relevant clauses of EN 60601-1-12:2015 apply.		P
	If a medical device is designated as "portable" (except patient handling equipment according to Table 9 it shall — be possible to be carried by one person; — have its own built in power supply (where relevant); — be capable of use outside the vehicle.	Fixed equipment	N/A
<b>6.3.2</b>	<b>Temperature</b>		P



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EN 1789:2020			
Clause	Requirement	Remarks	Verdict
	Medical devices shall comply with 4.2 of EN 60601-1-12:2015 and with requirements related to environmental conditions in relevant particular medical device standards as listed in Tables 9 to 16 as applicable.		P
<b>6.3.3</b>	<b>Humidity and ingress of liquids</b>		P
	Medical devices shall comply with 4.2 of EN 60601-1-12:2015 and with requirements related to environmental conditions in relevant particular medical device standards as listed in Tables 9 to 16 as applicable.		P
<b>6.3.4</b>	<b>Mechanical strength</b>		P
	Medical devices shall comply with EN 60601-1-12:2015, Clause 10.1 and with requirements related to mechanical strength in relevant particular medical device standards as listed in Tables 9 to 16 as applicable.		P
<b>6.3.5</b>	<b>Fixation of devices</b>		P
	Medical devices shall be restrained by means of a fixation system, retention or storage system, as appropriate.	The medical device can be restrained by a specified fixation holder	P
	If a charging device in the fixation system is present it shall automatically connect when fixed in the fixation system.		N/A
	The fixation system(s), retention system(s) or storage system(s) shall hold the device to withstand accelerations or decelerations of 10 g longitudinal (forward, backward), 10 g transverse (left, right) and 10 g vertical. This is to be tested as described in subclause 5.3.		P
	Terminal units and electrical socket outlets shall not be used as part of the fixation system.		P
	If rails systems are used, they shall comply with EN ISO 19054:2006+A1:2016.	No rails systems are used	N/A
<b>6.3.6</b>	<b>Electrical safety</b>		P
	All medical devices shall be selected and mounted so that no harmful influences to the electrical supply results.	No harmful influences to the electrical supply results	P
<b>6.3.7</b>	<b>User interface</b>		P



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EN 1789:2020			
Clause	Requirement	Remarks	Verdict
	Buttons, switches, indicators and controls shall be easily accessible and visible from the attendant's seat. SI units (except for blood pressure and airway pressure) and standardized graphical symbols shall be used where applicable.	Could be easily accessible and visible and numeric indications of parameters were expressed in SI units. Standardized symbol used	P
<b>6.3.8</b>	<b>Gas installation</b>	Not road ambulance	N/A
<b>6.3.8.1</b>	<b>Source of supply</b> The source of supply shall consist of one or more of the following: a) medical gas in cylinders, e.g. oxygen, air; b) non-cryogenic liquid in cylinders, e.g. N2O, CO2; c) cryogenic liquid in cylinders, e.g. oxygen; d) cryogenic liquid in stationary vessels, e.g. oxygen; e) non-cryogenic liquid in stationary vessels, e.g. N2O, CO2; f) air compressor system; g) proportioning system, e.g. oxygen and nitrogen; h) vacuum system; i) oxygen 93 %.		N/A
<b>6.3.8.2</b>	<b>Medical gas piping</b> All ducts for medical gas installations or medical gas piping shall be vented. If the road ambulance is intended to carry a transport incubator system there shall be an adapter for medical gases cross-border transportation meeting the requirements of EN 13976-1:2018 subclause 4.3.3.		N/A
<b>6.3.8.3</b>	<b>Flexible hoses for connecting devices</b> Flexible hoses for connecting medical devices to outlet connectors (i.e. terminal units or a gas-specific connection points) shall comply with EN ISO 5359:2014+A1:2017.		N/A
<b>6.3.8.4</b>	<b>Flexible hoses for medical gas supply</b>		N/A
	If flexible hoses are used for medical gas supply between the pressure regulators and the terminal units, the requirements of prEN ISO 11197:2018 apply.		N/A
<b>6.3.8.5</b>	<b>Stationary oxygen supply</b>		N/A



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EN 1789:2020			
Clause	Requirement	Remarks	Verdict
	The stationary oxygen supply shall comprise a source in accordance with Table 11 (under normal temperature and pressure) pressure regulators and terminal units or pressure regulators with flow metering devices.		N/A
<b>6.3.8.6</b>	<b>Portable oxygen supply</b>		N/A
	The portable oxygen supply shall comprise a source in accordance with Table 11 (under normal temperature and pressure) and a pressure regulator with flow metering device.		N/A
<b>6.3.8.7</b>	<b>Pressure regulators and flow metering devices</b>		N/A
	Pressure regulators and pressure regulators with flow metering devices shall conform to EN ISO 10524-1:2019 or EN ISO 10524-2:2019 or EN ISO 10524-3:2019. The pressure regulators shall be directly connected to the source of supply.		N/A
	Flow metering devices for connection to terminal units and for connection to flow-rate control units shall conform to EN ISO 15002:2008.		N/A
<b>6.3.8.8</b>	<b>Terminal units</b>		N/A
	Terminal units shall comply with prEN ISO 9170-1:2017.		N/A
<b>6.3.8.9</b>	<b>Pneumatic power supply</b>		N/A
	If the road ambulance is equipped with terminal units, the range of operating pressure shall be <ul style="list-style-type: none"> <li>— for compressed medical gases      <math>400\text{kPa}_0^{+100}\text{kPa}</math>; for tolerances see EN ISO 7396-1:2016+A1:2019, Table 2.</li> <li>— for vacuum      <math>\leq 60\text{ kPa}</math> absolute pressure</li> </ul>		N/A
	and the maximum allowable pressure change between the source of supply and the terminal units shall be <ul style="list-style-type: none"> <li>— for compressed medical gases      10 % at a flow of 40 l/min;</li> <li>— for vacuum      20 % at a flow of 25 l/min.</li> </ul>		N/A
<b>6.3.8.10</b>	<b>Additional outlet connectors</b>		N/A
	For road ambulances complying with 6.3.8.9, one additional outlet connector (i.e. a terminal unit or a gas-specific connection point) complying with prEN ISO 9170-1:2017 shall be fitted in addition to the outlet connectors necessary for the devices intended to be normally used.		N/A



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EN 1789:2020			
Clause	Requirement	Remarks	Verdict
<b>6.3.8.11</b>	<b>Pin-index cylinder values</b>		N/A
	Pin-index outlet connections of cylinder values shall comply with EN ISO 407:2004.		N/A
<b>6.3.8.12</b>	<b>Alarms</b>		N/A
	If alarms are provided as part of the gas installation, they shall comply with EN ISO 7396-1:2016+A1:2019, Clause 6.		N/A
<b>6.3.8.13</b>	<b>Test pressure for mechanical integrity</b>		N/A
	The gas piping and flexible hoses used for medical gas supply shall withstand a pressure of 1 000 kPa +20 % for at least 5 min.		N/A
<b>6.3.8.14</b>	<b>Test pressure for leakage</b>		N/A
	After a test period of 2 h to 24 h at nominal distribution pressure, the pressure drop in the gas piping of the distribution system shall not exceed 0,4 %/h of the test pressure.		N/A
	After a test period of 2 h to 24 h at nominal distribution pressure, the pressure drop in flexible hoses for medical gas supply of the distribution system shall not exceed 0,6 %/h of the test pressure.		N/A
<b>6.3.9</b>	<b>Marking and instructions</b>		P
	Marking and instructions for use shall comply with EN ISO 15223-1:2016 and EN 1041:2008+A1:2013.	See attached copy of Marking plater and refer to Instruction For Use	P
	Operating and maintenance instructions, service records and any other appropriate requirements shall accompany the product. Standardized symbols should be used or it should be written in the native language of the area where the equipment is to be used.	Refer to Instruction For Use	P
<b>6.3.10</b>	<b>Maintenance</b>		P
	The manufacturer shall supply instructions for carrying out preventive maintenance.	Refer to Instruction For Use	P
<b>6.4</b>	<b>List of equipment</b>		--
	Road ambulance according to their type A1, A2, B or C shall carry the minimum equipment listed in Tables 9 to 19.		N/A



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EN 1789:2020			
Clause	Requirement	Remarks	Verdict
	Where national regulations for equipment are in conflict with Tables 9 to 19 the national regulations apply. Supplementary devices may be introduced depending on local requirements.		N/A
	However, if it is common practice for the road ambulances to cross national borders, equipment according to Tables 9 to 19 shall be carried in accordance with the vehicle type.		N/A
	For most items a specific quantity is given. "X" in the column indicates that quantity may be varied in accordance with the local needs of the country/district.		N/A
	Where applicable the equipment shall be available across the full age range of patients.		N/A



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**Test data table:**

Table 5.3.1 Performance test after fixation test			P
Test item	Expected result	Test result	Verdict
Basic safety - Leakage current test	Test Method Refer to IEC 60601-1, clause 8.7	Not exceed specified limits	P
Basic safety - Dielectric strength test	Test Method Refer to IEC 60601-1, clause 8.8.3	No dielectric breakdown	P
Defibrillation energy (Load 50Ω)	Set: 360J Measure: 360J	Measure: 353.4J	P
Defibrillation energy (Load 50Ω)	Set: 100J Measure: 100J	Measure: 96.5J	P
Supplementary information: 1) Functional testing according to the test protocol provided by applicant 2) Accuracy requirements for defibrillation energy, the measured DELIVERED ENERGY into the load resistances of 50Ω, did not deviate from the DELIVERED ENERGY for that impedance by more than +/- 15 %.			



<b>Table 6.3.2 and 6.3.3: Performance test after temperature, humidity and ingress of liquids treatment</b>					<b>P</b>
Condition: 4.2 of EN 60601-1-12:2015					--
Test item	Expected result	4.2.1 Transport and storage	4.2.2.1 Continuous operating	4.2.2.2 Transient operating	Verdict
Basic safety - Leakage current test	Test Method Refer to IEC 60601-1, clause 8.7, IEC 60601-2-4 sub-clause 201.8.7	Not exceed specified limits	Not exceed specified limits	Not exceed specified limits	P
Basic safety - Dielectric strength test	Test Method Refer to IEC 60601-1, clause 8.8.3	No dielectric breakdown	No dielectric breakdown	No dielectric breakdown	P
Defibrillation energy (Load 50Ω)	Set: 360J Measure: 360J	Measure: 353.4J	Measure: 353.4J	Measure: 353.4J	P
Defibrillation energy (Load 50Ω)	Set: 100J Measure: 100J	Measure: 96.5J	Measure: 96.5J	Measure: 96.5J	P
Supplementary information: 1) Functional testing according to the test protocol provided by applicant 2) Accuracy requirements for defibrillation energy, the measured DELIVERED ENERGY into the load resistances of 50Ω, did not deviate from the DELIVERED ENERGY for that impedance by more than +/- 15 %.					

<b>Table 6.3.4 Performance test after mechanical strength test</b>				<b>P</b>
Condition: EN 60601-1-12:2015, Clause 10.1.3				--
Test item	Expected result	Test result	Verdict	
Basic safety - Leakage current test	Test Method Refer to IEC 60601-1, clause 8.7	Not exceed specified limits	P	
Basic safety - Dielectric strength test	Test Method Refer to IEC 60601-1, clause 8.8.3	No dielectric breakdown	P	
Defibrillation energy (Load 50Ω)	Set: 360J Measure: 360J	Measure: 353.4J	P	
Defibrillation energy (Load 50Ω)	Set: 100J Measure: 100J	Measure: 96.5J	P	



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Table 6.3.4 Performance test after mechanical strength test			P
Condition: EN 60601-1-12:2015, Clause 10.1.3			--
Test item	Expected result	Test result	Verdict
Supplementary information: 1) Functional testing according to the test protocol provided by applicant 2) Accuracy requirements for defibrillation energy, the measured DELIVERED ENERGY into the load resistances of 50Ω, did not deviate from the DELIVERED ENERGY for that impedance by more than +/- 15 %.			



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**Attachment 1: Static test method for clause 5.3 and 6.3.5**

Mounting system test conditions

Test items	Standard	Test conditions
Mounting system test (static test)	EN 1789:2020	Determined the equipment mass and center of gravity; the equipment under test is mounted on the mounting bracket provided by manufacturer, the mounting bracket is fixed on the flat fixed holder. Through the centroidal of equipment under test, along the longitudinal direction (forward, backward), lateral (left, right) and vertical (downward) are applied is equivalent to 10 times the weight of equipment under test.

**Test method:**

Static test is selected for this test protocol, The principle of static test is as follows:

Put the equipment on the platform with low friction, using weights, pulley and other combination to simulate the acceleration of the vehicle impact.

Remark: there are no fixed holder of road ambulances provided by manufacture, it is provided by testing laboratory, therefore, this test is only to test if the equipment rolls from mounting bracket under 10 g accelerations.

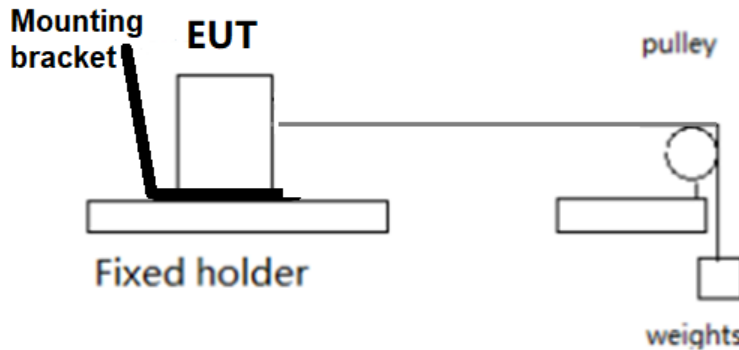


Figure 1: the principle of static test

$F=ma$  : the pulling force: 250N

m:the quality of equipment under test:2.5kg

$a=10g$ .

So, weights quality is 25kg

Other axial methods are similar to the figure above.

**Attachment 2: Photo documentation**

Details of: i9 Plus with mounting bracket

View:

- general
- front
- rear
- right
- left
- top
- bottom



Details of: i9 Plus with mounting bracket

View:

- general
- front
- rear
- right
- left
- top
- bottom



**Attachment 2: Photo documentation**

Details of:           i9 Plus          



Details of:           i9 Plus          



**-- End of report --**

