Ministry of Health

ORDER No. 2.219
of 14 July 2022

regarding the control through periodic check of in-use medical devices, the evaluation of the performance of the second-hand medical devices put into operation and the issuance of an approval for use of the medical devices as equipment of healthcare units and of means of intervention for pre-hospital emergency medical assistance

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On seeing approval report no. 12.079 of 14.07.2022 of the Pharmaceutical and Medical Devices Directorate and the notification of the National Agency for Medicines and Medical Devices of Romania no. 50.259 of 10.01.2022, registered at the Ministry of Health with no. P 0056 of 11.01.2022,

taking into account the provisions of:

- Art. 928, Art. 930 paragraph (1) letters c) and d), Art. 931 paragraph (1) and of Art. 932 paragraph (1) of Law 95/2006 on healthcare reform, republished, as further amended and supplemented;
- Art. 4 paragraph (4) points 1 and 25 - 28 of Law 134/2019 on reorganisation of the National Agency for Medicines and Medical Devices and amendment of further ruling provisions, as further amended and supplemented,

pursuant to Article 7 paragraph (4) of Government Decision No. 144/2010 on organisation and operation of the Ministry of Health, as further amended and supplemented,

the minister of health hereby issues the following order:

Section I
General provisions

Art. 1 - This Order regulates:

a) in-use medical devices which must undergo periodic check, as well as the evaluation of the performance of the second-hand medical devices put into operation, in line with the provisions of Art. 928 and Art. 931 paragraph (1) of Law 95/2006 on healthcare reform, republished, as further amended and supplemented;

b) issuing an approval for use for medical devices as equipment of healthcare units and of means of intervention for pre-hospital emergency medical assistance.

Art. 2 - (1) Within the meaning of this Order, the definitions mentioned in Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC – hereinafter referred to as the ***Regulation,*** shall apply.

(2) Within the meaning of this Order, the terms and concepts used have the following meanings:

a) ***control through periodic check of a medical device*** **-** set of activities carried out for the purpose of evaluating the maintenance of certain characteristics established by the manufacturer or by an authority in the field;

b) ***the specified limit of a parameter value*** - tolerance range around a set value or a minimum

or maximum allowed value; this is mentioned in standards/rules/instructions or in the medical device's technical specification;

c) ***acceptance criterium*** - the minimum requirement which must be met by the medical device subject to check;

d) ***set of acceptance criteria*** - set of characteristics of a medical device specimen, such as defining parameters, configuration and accessories, including software, general technical condition, which confer an adequate level of confidence regarding fulfilment of the main specific essential requirements;

e) ***second-hand medical devices, other than those for diagnosis and treatment using ionizing radiation, nuclear medicine and magnetic resonance imaging (MRI)*** - electrically powered medical devices, with CE marking, out of the warranty period granted by the manufacturer/manufacturer's representative, which are introduced and put into operation for the first time on the Romanian market, previously owned and used and which are subsequently distributed with or without payment for subsequent use for the same purpose for which they were manufactured;

f) ***maintenance*** - set of activities aimed at maintaining or restoring the state of a medical device in operating conditions according to its intended purpose;

g) ***defining parameter*** - physical size or characteristic function of a medical device whose deviation from the specified limits may lead to the emergence of a risk in the medical act;

h) ***second-hand medical devices for diagnosis and treatment using ionizing radiation, nuclear medicine and magnetic resonance imaging (MRI)*** - electrically-powered medical devices with CE marking, out of the warranty period granted by the manufacturer/manufacturer's representative, which are placed for the first time or are in use on the Romanian market and which, after their prior uninstallation, are subsequently put into operation for subsequent use for the same purpose for which they were manufactured;

i) ***evaluation of the performance of the second-hand medical devices*** - set of activities carried out for the purpose of assessing the maintenance of certain characteristics established by the manufacturer or by an authority in the field to achieve the proposed purpose, such as the overall technical condition, labelling/identification, presence of the CE marking, physical integrity, functionality of controls and alarms, configuration and accessories, measurement of defining electrical safety/performance parameters, as appropriate;

j) ***means of intervention for pre-hospital emergency medical assistance*** - set of means used within the National System for Emergency Medical Assistance and Qualified First Aid for: assisted medical transport, unassisted medical transport, air rescue missions, naval rescue missions or emergency home consultations.

Section II
Control through periodic check of medical devices

Art. 3 - Medical devices in the equipment of health units and the means of intervention for pre-hospital emergency medical assistance which are subject to control through periodic check, as well as periodicity of the checks, are provided in Annex 1.

Art. 4 - (1) The control through periodic check of medical devices consists of the following set of activities:

a) evaluation of defining safety parameters, through examination and testing;

b) evaluation of defining performance parameters, through examination and testing;

c) check of fulfilment of the set of acceptance criteria for the medical device - imposed values, specified limits, accessories;

d) issuance of a test report containing the results obtained from examinations and tests. If the

medical device does not meet the acceptance criteria, a negative test report is issued, prohibiting the use of the medical device until the non-compliances are eliminated and the checks are resumed;

e) issuance of a periodic check bulletin.

(2) By way of exemption from the provisions of paragraph (1), the issuance of the periodic inspection bulletin for the types of medical devices provided for in point 2 of Annex 1 shall be based on the test reports issued by the National Agency for Medicines and Medical Devices of Romania, hereinafter referred to as the ***ANMDMR***, following performance of test radiographs and visual inspection of the equipment at the ANMDMR headquarters or following evaluation of test radiographs and identification or evaluation photos taken according to the specific technical procedures of the ANMDMR and made available by the user.

(3) By way of exemption from the provisions of paragraph (1), for the types of medical devices provided for in points 7, 8, 9, 10 and 11 of Annex 1, the issuance of the periodic check bulletin may be made on the basis of the technical inspection bulletin, issued by an economic operator approved by the ANMDMR and, where applicable, by the National Commission for Nuclear Activities Control, hereinafter referred to as the ***CNCAN***, with which the user has concluded a service contract. Technical inspection bulletins for the medical devices provided for in points 7, 8, 9, 10 and 11 of Annex 1 must be valid for at least 30 days after issuance of the periodic check bulletin by the ANMDMR.

Art. 5 - (1) The control through periodic check of medical devices provided for in Art. 4 is carried out by the ANMDMR's own laboratories.

(2) Medical devices to which regulatory acts in the field of activity of other authorities or public institutions apply, namely the county public health departments and the Bucharest municipality, the CNCAN or the State Inspectorate for the Control of Boilers, Pressure Vessels and Lifting Installations, hereinafter referred to as the ISCIR, must comply with all applicable regulations.

(3) The first periodic inspection of the medical devices included in Annex 1 shall be carried out within a period of up to 3 years from the date of expiry of the warranty period.

(4) The application for renewal of the periodic check bulletin must be submitted to the ANMDMR at least 6 months before expiry of the validity of previously issued notice/bulletin.

Art. 6 - By way of exemption from the periodicity of the checks provided for in Annex 1, if one of the measured values of the defining parameters is close to the specified permitted limits or in the case of medical devices which have exceeded the maximum limit of the normal operating duration, a validity period shorter than the one provided for in Annex 1 may be established in the check bulletin.

Art. 7 - (1) Control through periodic check is carried out according to the specific technical procedures in the field of medical devices developed by the ANMDMR.

(2) Electrical safety checks are carried out in line with the provisions of the current editions of standards SR EN 60601-1, SR EN 61010-1, SR EN 62353 and other applicable standards, as appropriate.

Art. 8 - (1) Second-hand medical devices provided free of charge or for a fee can be used after commissioning, only following the evaluation of performances by the ANMDMR, based on the approval issued by the ANMDMR.

(2) The performance assessment of second-hand medical devices provided for in Art. 931 paragraph (1) of Law 95/2006, republished, as further amended and supplemented, is carried out by the ANMDMR with its own laboratories.

(3) The opinion provided for in paragraph (1), called the approval for use, is issued according to the technical procedures developed by the ANMDMR.

(4) The ANMDMR may issue the approval referred to in paragraph (1) only if, at the date of the first introduction on the Romanian market, the second-hand medical device with CE marking has at least 3 years left until reaching the maximum limit of the normal operating life is reached, the importer or distributor being obliged to comply with this requirement.

(5) Healthcare units are obliged, after putting into operation a second-hand medical device with CE marking, to immediately request the ANMDMR to assess its performance in order to issue the approval for use. In this case, the second-hand medical device with the CE marking, at the date of the first introduction on the Romanian market, has at least 3 years left until reaching the maximum limit of the normal operating life.

(6) For second-hand medical devices which do not have the year of manufacture marked on the casing or label, the importer, respectively the distributor and the healthcare units are obliged to make available to the representatives of the ANMDMR the relevant documents showing the age of the equipment. If these documents cannot be made available, it is considered that the second-hand medical device does not meet the age requirements set out in paragraphs (4) and (5) and a decision rejecting the application is issued by the president of the ANMDMR.

(7) The provisions of this article also apply to medical devices as equipment of means for intervention for pre-hospital emergency medical assistance.

Art. 9 - (1) Medical devices as equipment of intervention means for pre-hospital emergency medical care may be used only on the basis of the approval for use issued by the ANMDMR through its own laboratories.

(2) The approval of medical devices as equipment of intervention means for pre-hospital emergency medical care is carried out according to the specific technical procedures in the field of medical devices, developed by the ANMDMR.

(3) Approval activities refer both to the evaluation of the defining performance parameters of medical devices and to the check of the existence of the minimum mandatory equipment with medical devices, according to the request of the applicant/beneficiary correlated with the provisions of Annex 2.

(4) Approval activities are carried out at the ANMDMR headquarters. In the case of beneficiaries who have a number of intervention means for pre-hospital emergency medical care greater than 10 units, the approval activity is carried out by a team of specialists from the ANMDMR, at the headquarters of the respective health unit.

(5) The approval for use for medical devices as equipment of pre-hospital emergency medical care intervention means is not their authorisation, but rather an assessment of the minimum mandatory equipment and of the performance of the medical devices.

Art. 10 - (1) The approval of medical devices from the equipment of the intervention means for pre-hospital emergency medical assistance involves, successively, the following activities:

a) check of the existence of the minimum mandatory equipment with medical devices according to Annex 2. If medical devices or equipment/materials are missing from the minimum mandatory equipment corresponding to the classification requested by the beneficiary, a negative test report is issued in which the discovered non-compliance will be mentioned;

b) evaluation of the defining performance parameters, through examination and testing. Since, by their nature, the medical devices as equipment of means of intervention for pre-hospital emergency medical assistance must operate independently, with batteries, all checks or tests are made with them unconnected to the electricity network. Stationary mucus aspirators are the exception to this rule, which by their nature can be powered from the available sockets as equipment of mobile intervention units;

c) check of the fulfilment of the set of acceptance criteria for medical devices - imposed values, specified limits, accessories;

d) issuing a test report containing the results obtained from the examinations and tests. If a medical device does not meet the acceptance criteria, a negative test report is issued prohibiting the use of the medical device until the non-compliances are eliminated and the checks are resumed, after submitting a new application;

e) issuing the approval for use for medical devices as equipment of intervention means for pre-hospital emergency medical care. The approvals for use have a validity period in accordance with the periodicity of the checks provided for in Annex 1. By way of exemption from this rule, for those medical devices as equipment of intervention means for pre-hospital emergency medical care which do not fall under the scope of this order, the validity period of the issued approval for use is no longer specified, because the respective medical devices are not subject to periodic check.

(2) The test report provided for in paragraph (1) letter d) shall not be issued if the pre-hospital emergency medical assistance intervention device is equipped with:

a) new medical devices under warranty, namely mucus aspirators, external cardiac defibrillators, pulmonary ventilators, neonatal transport incubators, vital function monitors, electrocardiographs, injection machines;

b) medical devices which are not new, under warranty, other than those provided for in Art. 8 paragraph (1), which are not provided for in Annex 1, namely mucus aspirators and injection machines, and which have a technical inspection certificate less than one year old, issued by an economic operator approved by the ANMDMR.

Art. 11 - (1) The approval of medical devices as equipment of emergency medical intervention means for pre-hospital care shall be carried out in compliance with the provisions of the specific technical procedures of the ANMDMR, in the following situations:

a) upon first commissioning on the territory of Romania, in the case of second-hand emergency medical intervention means for pre-hospital care;

b) when the applicant or beneficiary wishes to change the classification from a lower to a higher level. The initial classification obtained following issuance of the approval for use does not prevent the reclassification of emergency medical intervention means for pre-hospital care from a higher to a lower level, the responsibility for reclassification or reclassification falling entirely on the management staff of the public or private ambulance service. A means of intervention for pre-hospital emergency medical assistance may be reclassified from a higher to a lower level only until the next periodic technical inspection or until the issue which led to reclassification is solved, provided that the ambulance equipment complies with all minimum requirements set out in Annex 2 for the new type of classification;

c) when the applicant or beneficiary who already has an expired approval for use wishes to replace one or several medical devices provided for in Annex 1, replacement is made with:

1. second-hand medical devices of the type provided for in Art. 8 paragraph (1);

2. medical devices whose warranty certificate is no longer valid;

3. medical devices which do not have an expired approval for use or check certificate issued by the ANMDMR;

d) upon change of owner/beneficiary.

(2) For new means of intervention for pre-hospital emergency medical assistance, namely new motor vehicles, equipped by an approved manufacturer with new medical devices, under warranty, which have a declaration of compliance issued by the approved manufacturer who equipped and bodyworked the ambulance, no approval for use is issued.

(3) Means of intervention for pre-hospital emergency medical assistance subject to evaluation may be equipped with:

a) second-hand medical devices or those no longer under warranty;

b) new medical devices, under warranty;

c) second-hand medical devices or those no longer under warranty and new medical devices under warranty.

(4) Second-hand pre-hospital emergency medical assistance means must have a registration certificate or identity card showing that they were last registered as ambulances, which certifies that a competent authority has established that they were designed and built in accordance with the regulations in force.

Art. 12 - (1) In order to obtain the approval for use, the applicant/representative of the healthcare unit submits an application to the ANMDMR, which will be accompanied by supporting documents.

(2) In order to obtain the approval for use, the following supporting documents are required, cumulatively:

a) copy of the sanitary operating authorisation

The applicant/beneficiary of the application for an approval for use must be authorised to carry out activities related to human health.

Newly established companies which do not have a sanitary operating authorisation must have a registration certificate issued by the National Trade Register Office, which must show that the company carries out activities related to human health. In this case, the applicant must submit a statutory declaration (affidavit) to the file by which he undertakes to send a copy of the sanitary operating authorisation to the ANMDMR after obtaining it.

Private law associations without patrimonial purpose must have the activities related to human health mentioned in the statute as a field of activity.

b) copy of the registration certificate or identity card of the means of intervention for pre-hospital emergency medical assistance showing that it was last registered as an ambulance (only for second-hand vehicles);

c) copy of the documents of origin for the means of intervention for pre-hospital emergency medical assistance;

d) copy of the documents of origin for medical devices in the equipment, namely mucus aspirators, external cardiac defibrillators, pulmonary ventilators, neonatal transport incubators, vital function monitors, electrocardiographs, injection machines. The affidavit is not accepted as a source document. For new medical devices under warranty, a copy of the warranty certificate is also requested, which must mention the equipment's manufacturing series;

e) confirmation of payment of the evaluation fee calculated in line with the Order of the Minister of Health approving the fees charged by the ANMDMR for activities in the field of medical devices.

The ANMDMR may additionally request any other documents considered relevant for the purpose of issuing the approval for use.

(3) The applicant/beneficiary of the application for approval for use is obliged to ensure the traceability of the origin of the medical devices, in line with the provisions of the Regulation. Ensuring traceability is no longer necessary if the medical devices already have an approval for use or check bulletin previously issued by the ANMDMR.

(4) If the applicant differs from the beneficiary of the application for issuance of an approval for use, all documents attached to the application referred to in paragraph (1), namely the operating documents of the economic operator, the documents of origin for the intervention means for pre-hospital emergency medical care and the medical devices, as well as their warranty certificates, must be issued in the name of the beneficiary of the application, respectively in the name of the person who is to use the mobile intervention unit.

Art. 13 - (1) Medical devices such as mucus aspirators, external cardiac defibrillators,

pulmonary ventilators, neonatal transport incubators, vital function monitors, electrocardiographs, injection machines must have a technical book or user manual or work instructions and the CE compliance marking.

(2) New medical devices under warranty, such as mucus aspirators, external cardiac defibrillators, pulmonary ventilators, neonatal transport incubators, vital signs monitors, electrocardiographs, injection machines, must have valid warranty certificates. The manufacturing series of the medical devices must be clearly stated on the warranty certificates.

(3) New and second-hand medical devices originating from donations must have a donation notice issued by the ANMDMR and comply with all provisions of Order of the Minister of Health 1032/2011 on approval of Norms concerning donations of medicinal products, medical supplies, medical devices, vaccines, sera and related supplies, as further amended and supplemented.

(4) If for the means of intervention for pre-hospital emergency medical assistance, medical devices or their components there are express regulations in the field of activity of some authorities or public institutions, such as the ISCIR, the Romanian Auto Registry, the county public health departments and the Bucharest municipality or other public authorities and institutions in the field of road, naval or aeronautical means of transport, then the responsibility for obtaining specific approvals for them lies with the owner or user, the authorised natural person, the economic operator or the manufacturer who modifies and/or equips the means of intervention for pre-hospital emergency medical assistance.

Art. 14 - (1) The approval procedure can only be started after payment of the related fee provided for in Art. 12 paragraph (2) letter e). The fee proposal is issued after the working file is complete.

(2) If the assessment was carried out at the beneficiary's premises, the documents prepared by the ANMDMR shall be sent to the beneficiary only after payment of travel expenses and receipt of payment confirmation. In case of failure to pay travel expenses, the beneficiary cannot receive the approval for use.

Art. 15 - (1) For the purpose of the approval, all medical devices, equipment and items inside the pre-hospital emergency medical care intervention means must be secured in such a way that they do not become potentially dangerous when subjected to forces due to sudden acceleration/deceleration, such as in the event of an impact. The responsibility for securing the equipment lies entirely with the beneficiary.

(2) For automated external cardiac defibrillators, hereinafter referred to as ***AEDs***, it is mandatory that the operating menu and the voice instructions for guiding resuscitation are in Romanian or English. Any AED that has a menu or instructions in another language is considered non-compliant and a negative test report is issued for it. Automated defibrillators in the equipment of mobile intervention units operating in areas of the country where the majority population is of another ethnic origin are exempt from the previously provided rule, these defibrillators being able to have a menu or instructions in the language of the respective ethnic groups.

Art. 16 - (1) The request provided for in Art. 12 paragraph (1) shall be cancelled and archived if:

a) The ANMDMR requested via a sent notification or e-mail the correct completion of the application and/or additional documents to those already submitted by the applicant, and the applicant did not send the ANMDMR all requested information and documents within a maximum period of 10 working days from receipt of the request;

b) the applicant has not paid the evaluation fee according to the invoice issued by the ANMDMR. If, after paying the evaluation fee, the applicant wishes to change the type of mobile intervention unit mentioned in the initial application, a percentage of 25% will be

retained from the amount paid, representing the equivalent value of the analysis service of the cancelled and archived application. The remaining difference will be used to cover the expenses related to the new application, in which the modified classification is specified;

c) the beneficiary did not show up for two consecutive appointments, which were made in agreement with ANMDMR representatives. An exception to this rule is the case where the beneficiary announces the impossibility of showing up by the settled deadline, impossibility on behalf of a valid reason: technical issues with the vehicle, medical situations and the like.

(2) In the situations provided for in paragraph (1), if the applicant wishes to obtain the approval for use, he must submit a new application to the ANMDMR.

Art. 17 - (1) An approval for use issued by the ANMDMR may be cancelled if the owner of a means of intervention for pre-hospital emergency medical assistance requests:

a) change of classification compared to the previous classification;

b) issuance of a new approval for use following the replacement of medical devices from the equipment of a means of intervention for pre-hospital emergency medical care which already had an approval for use;

c) taking over medical devices from another means of intervention for pre-hospital emergency medical care which already had an approval for use.

(2) In the situations provided for in paragraph (1), at the assessment made in order to obtain the new approval for use, the beneficiary must present the approval for use previously issued by the ANMDMR, on which the stamp with the mention "cancelled document", the date and signature of the legal representative of the ANMDMR are applied.

Art. 18 - (1) In extraordinary situations, which cannot be foreseen and which are related to general public interest, such as for example the state of emergency established by decree issued by the President of Romania, in case evaluations of medical devices in the equipment of intervention means for pre-hospital emergency medical care cannot be carried out at the ANMDMR headquarters and the approvals for use provided for in Art. 9 paragraph (1) cannot be issued, the ANMDMR may issue a temporary approval for use with a validity period of 3 months for the medical devices in the equipment of intervention means for pre-hospital emergency medical care.

(2) The validity period provided for in paragraph (1) may be extended beyond the 3-month period, by decision of the President of the ANMDMR, depending on the context of the situation existing at that time, until the end of the extraordinary situation established according to the law, but not more than 3 years.

(3) Temporary approvals for use provided for in paragraph (1) shall be identified by the initial T accompanying the number of the approval for use.

(4) Upon termination of the validity of the temporary approval for use provided for in paragraph (1), the beneficiaries are obliged to report to the ANMDMR headquarters in order to carry out technical checks and issue the final approval for use.

Section III
Final provisions

Art. 19 - (1) Healthcare units are required to periodically check all medical devices in use and which are provided for in Annex 1. The control is carried out by the ANMDMR, regardless of whether or not the healthcare units have concluded a contract with health insurance companies, as the case may be.

(2) All holders of intervention means for pre-hospital emergency medical assistance who are in one of the situations provided for in Art. 11 paragraph (1) are obliged to take the steps to obtain the approval for use provided for in Art. 9 paragraph (1).

(3) Healthcare units, at the request of the ANMDMR, are obliged to ensure the participation in performed checks of specialists from economic operators with whom they have concluded service contracts for medical devices subject to control through periodic check or performance evaluation of second-hand medical devices and who have performed maintenance services.

Art. 20 - Health units have the following obligations:

a) to nominate a person responsible for maintaining records of medical devices in use and as a contact person in relation to the ANMDMR;

b) to establish a registry of medical devices in use, which shall expressly mention:

1. name/type of medical device;
2. manufacturer, country of origin;
3. series/year of manufacture, inventory number;
4. document of origin;
5. date of commissioning;
6. records of repairs and other maintenance operations, as well as those who performed them;
7. records of controls through periodic check;
8. involvement in possible incidents in use (date, location, description of the incident, responsible personnel, corrective actions, etc.);
9. internal movement within the unit (where it comes from, new place of use, date, etc.);

a) to ensure planning for the control through periodic check of medical devices in use under the conditions of this Order.

Art. 21 - (1) It is prohibited to use medical devices which do not comply with the tests carried out during periodic check or performance evaluation of second-hand devices.

(2) After elimination of non-compliances, the medical devices referred to in paragraph (1) shall be subject to a new check in order to issue the periodic check certificate or the approval for use.

(3) For failure to comply with the provisions of this Order, the sanctions provided for in Art. 935 points b) - g) of Law 95/2006, republished, as further amended and supplemented, shall apply.

(4) In the case of applications submitted to the ANMDMR for the issuance of the periodic check bulletin or the approval for use, which have not been resolved by the date of entry into force of this Order, healthcare units must send the updated application to the ANMDMR in accordance with the provisions of this Order, within 6 months.

Art. 22 – Order of the Minister of Health No. 308/2015 on control through periodic check of medical devices put into operation and in use, published in the Official Gazette of Romania, Part I, no. 194 of 24 March 2015, shall be repealed.

Art. 23 – Annexes 1 and 2 are integral parts of this Order.

Art. 24 – This Order shall be published in the Official Gazette of Romania, Part I.

On behalf of the Minister of Health,
Aurel-George Mohan,
Secretary of state

Annex 1

TYPES OF MEDICAL DEVICES
as equipment of healthcare units and of means of intervention for pre-hospital emergency medical assistance subject to control through periodic check and the periodicity of the checks

Medical device type	Periodicity
1. Installations which use ionizing radiation: - Fixed x-ray with 2 positions - Fixed x-ray with 1 position graphy - Fixed X-ray with 1 position-scopy-graphy - Mobile X-ray machine - C-arm mobile X-ray (scope-graph) Mammography X-ray	3 years, except for devices older than 15 years, with a 2-year periodicity
2. Radiological protection equipment	3 years
3. High-frequency electrosurgical devices	3 years, except for devices older than 12 years, with a 2-year periodicity
4. Complex ultrasound exploration systems (sonographs)	
5. Closed incubators for neonates and transport incubators	
6. External cardiac defibrillators	
7. Steam sterilizers	
8. Equipment for diagnosis or treatment using ionizing radiation, nuclear medicine or magnetic resonance, such as: - Dental (intraoral, panoramic, panoramic with cephalostat) X-ray - Angiograph - Osteodensitometer - Computed tomography - Magnetic Resonance Imaging (MRI) equipment - Computed tomography simulator - Radiotherapy simulator - Radiotherapy equipment (linear accelerator, Cobalt-60 Teletherapy Machine, brachytherapy machine) - Nuclear medicine equipment (Gamma camera, PET, SPECT, etc.)	3 years, except for devices older than 15 years, with a 2-year periodicity
9. Haemodialysis machines	3 years, except for devices older than 12 years, with a 2-year periodicity
10. Electrically and pneumatically operated anaesthesia and/or ventilation devices	
11. Medical devices with ECG function (electrocardiographs and monitors)	

Annex 2

LIST

of minimum mandatory medical devices, equipment and materials as equipment of means of intervention for pre-hospital emergency medical assistance

NOTE:

The equipment and materials in the Lists are only the minimum mandatory for each means of intervention for pre-hospital emergency medical assistance. Other equipment/materials considered necessary according to the type of intervention means and the category of personnel serving it may be added to these Lists.

I. Equipment for patient handling, immobilization and transport (minimum requirements)

No.	Equipment	1 C1	2 B1/C2	3 B2	4 A1	5 A2	6 MU	7 AMD	8 Helicopter	9 Plane	10 Ship
1	Stretcher support/Stretcher securing system during transport, independent damping system, the stretcher can be placed in the middle, left side and right side, allowing access to the patient from all sides, complying with the regulations of the SR EN 1789 standard	+	+ C2	-	-	-	-	-	-	-	-
2	Stretcher support/Stretcher securing system during transport placed on the side or in the middle	-	+ B1	+	+	-	-	-	+	+	+
3	Main stretcher (with wheels in the case of ambulances), with patient fixation system	+	+	+	+	-	-	-	+	+	+
4	Scoop stretcher	+	+	+	-	-	-	-	-/+	-	-/+
5	Vacuum mattress	+	+	+	-	-	-	-	+	+	+
6	Wheelchair (unless the main stretcher also has this function), with patient restraint system	+	+	+	+	+	-	-	-	-	-
7	Transport sheet or transfer mattress	+	+	+	+	+	-	-	+	+	+
8	Complete rigid spine stretcher (with head immobilization/fixation if head fixation is not included in the shovel stretcher)	+/-	+/-	+/-	-	-	-	-	+/-	+/-	+/-
9	Medical cabin heating system	+	+	+	+	+	-	-	+	+	+

10	Twin-engine in accordance with European regulations in force for air rescue helicopters	-	-	-	-	-	-	-	+	-	-
11	Traction device for femoral fractures	+	+	-/+	-	-	-	-	-/+	-	-/+
12	Vacuum or inflatable splint set	+	+	+	-	-	+	-	+	+	+
13	Cervical splints for adults/children, complete set or a minimum of 3 adjustable cervical collars to which paediatric sizes will be added	+	+	+	-	-	+	-	+	+	+

No.	Equipment	1 C1	2 B1/C2	3 B2	4 A1	5 A2	6 MU	7 AMD	8 Helicopter	9 Plane	10 Ship
14	KED (puller for axial immobilization of the head/neck and trunk for the extraction of injured persons from motor vehicles)	+	+	+	-	-	+	-	-/+	-	-
15	Infusion stand	+	+	+	+	-/+	-	-	+	+	+

II. Apparatus/Equipment for resuscitation-breathing (minimum requirements)

No.	Equipment	1 C1	2 B1/C2	3 B2	4 A1	5 A2	6 MU	7 AMD	8 Helicopter	9 Plane	10 Ship
1	Stationary oxygen - minimum 2 x 10 l, NTP, flow meter/flow valve with maximum capacity of at least 15 l/min. and regulating valve Quick connection	+	+	+	+	+	-	-	+ (5 litres)	+	+
2	Portable oxygen - minimum 5 l, NTP, flow meter/flow valve with maximum capacity of at least 15 l/min. and regulating valve Quick connection	+	+	+	+	+	+	+	+	+	+
3	Adult/child ventilation bag with masks of different sizes and additional oxygen tank	+ (2 pieces)	+	+	+	+	+	+	+ (2 pieces)	+ (2 pieces)	+
4	Adult/child oropharyngeal tract set	+ (2 pieces)	+	+	-	-	+	+	+ (2 pieces)	+ (2 pieces)	+
5	Laryngoscope with blades of different sizes (adult/child) and with mandrel	+ (2 pieces)	+	+	-	-	+	+	+ (2 pieces)	+ (2 pieces)	+
6	Magill forceps different sizes	+ (2 pieces)	+	-	-	-	+	+	+ (2 pieces)	+ (2 pieces)	+
7	Portable adult/child volumetric ventilator with PEEP and the possibility of connecting to a fixed oxygen source	+	+ C2	-	-	-	+	-	+	+	-
8	Intermediate mouthpiece ventilation (insufflation mask)	+	+	+	+	+	+	+	+	+	+

9	Electric stationary vacuum cleaner with a minimum 1 l tank capacity	+	+	+	-	-	-	-	+	+	+
10	Rechargeable electric portable vacuum cleaner with a minimum 1 l tank capacity	+	+	+	+	+	+	+	+	+	+

III. Monitoring-defibrillation-evaluation-medicinal product/solution administration equipment (minimum requirements)

No.	Equipment	1 C1	2 B1/C2	3 B2	4 A1	5 A2	6 MU	7 AMD	8 Helicopter	9 Plane	10 Ship
1	Manual defibrillator/ECG monitor with external pacemaker	+	+ C2	-	-	-	+	-	+	+	-
2	Semi-automatic defibrillator	-	+ B1	+	-	-	-	+	-	-	+
3	Automatic blood pressure monitor (can be integrated into the defibrillator, except for helicopters and airplanes)	+	+ C2	-	-	-	+	-	+	+	-

No.	Equipment	1 C1	2 B1/C2	3 B2	4 A1	5 A2	6 MU	7 AMD	8 Helicopter	9 Plane	10 Ship
4	Pulse oximeter (can be integrated into the defibrillator, except for helicopters and airplanes)	+	+	+	-	-	+	-	+	+	+
5	Capnometer (can be integrated into the defibrillator, except for helicopters and airplanes)	+	+ C2	-	-	-	+	-	+	+	-
6	Central thermometer (can be integrated into the defibrillator, except for helicopters and planes)	+	+ C2	-	-	-	+	-	+	+	-
7	ECG monitor with pulse oximeter, capnometer, invasive BP, non-invasive BP, central thermometer	-	-	-	-	-	-	-	+	+	-
8	Injection machine (automatic syringe)	+	+	-	-	-	+	-	+ (2 pieces)	+ (2 pieces)	-
9	Heating system for solutions for infusion	+	+	-	-	-	+	-	+	+	-
10	Glucometer	+	+	-	-	-	+	+	+	+	-
11	Stethoscope	+	+	+	-	-	+	+	+	+	+
12	Manual blood pressure monitor	+	+	+	-	-	+	+	+	+	+
13	Medical penlight	+	+	+	-	-	+	+	+	+	+
14	Reflex hammer	+	+	-	-	-	+	+	+	+	-
15	Pressure infusion bag	+	+	-	-	-	+	-	+	+	-

IV. Sanitary materials (minimum requirements)

No.	Equipment	1 C1	2 B1/C2	3 B2	4 A1	5 A2	6 MU	7 AMD	8 Helicopter	9 Plane	10 Ship
1	Yankauer suction tubes	+	+	+	+	+	+	+	+	+	+
2	Flexible endotracheal suction tubes/ (including for paediatric use)	+	+	+	-	-	+	+	+	+	+
3	5- and 10-ml syringes	+	+	+	-	-	+	+	+	+	+
4	Infusion kits	+	+	+	-	-	+	+	+	+	+
5	Syringes and injection kits	+	+	-	-	-	+	-	+	+	-
6	Tracheal intubation tubes (2.5, 3, 3.5, 4, 4.5, 5, 5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9, 9.5, 10)	+	+	-	-	-	+	-	+	+	-

7	Tracheal intubation tubes (6, 7, 8, 9)	-	-	+	-	-	-	+	-	-	+
8	Combitube/Easytube (2 sizes)	-	-	+	-	-	-	-	-	-	+
9	Laryngeal mask airway (LMA) (for adults/children)	+	-	-	-	-	+	-	+	+	-
10	Mini Tracheostomy Kit	+	+	-	-	-	+	-	+	+	-
11	Blankets - minimum 2	+	+	+	+	+	+	-	+	+	+
12	Sheet	+	+	+	+	+	-	-	+	+	+
13	Sterile and non-sterile dressings	+	+	+	-	-	+	-	+	+	+
14	Chest drainage kits (2 adults/2 children)	+	-	-	-	-	+	-	+	+	-
15	Special burn dressings and insulating foil	+	+	+	-	-	+	-	+	+	+

No.	Equipment	1 C1	2 B1/C2	3 B2	4 A1	5 A2	6 MU	7 AMD	8 Helicopter	9 Plane	10 Ship
16	"Replanting" container with internal temperature maintained at 4 ± 2° C, for at least 2 hours	+	+	+	-	-	+	-	+	-	+
17	Renal tray	+	+	+	+	+	-	-	+	+	+
18	Vomit bags	+	+	+	+	+	-	-	+	+	+
19	Urine collection kit/urine collection bags	+	+	-	-	-	-	+	+	+	-
20	Urinal bottle	+	+	+	+	+	-	-	+	+	+
21	Sharps container	+	+	+	+	+	+	+	+	+	+
22	Sondaj gastric	+	+	-	-	-	+	-	+	+	-
23	Sterile surgical gloves	+	+	-	-	-	+	-	+	+	-
24	Non-sterile/consultation/disposable gloves	+	+	+	+	+	+	+	+	+	+
25	Peripheral intravenous cannulas, various sizes for adults/children	+	+	+	-	-	+	+	+	+	+
26	Central I.V. access catheters	+	-	-	-	-	+	-	+	+	-
27	Paediatric intraosseous access needle	+	-	-	-	-	+	-	+	+	-
28	Suitcase/Backpack for portable intervention materials	+	+	+	-	-	+	+	+	+	+