Information Medical Supply Units

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Medical supply units

Contents

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Medical Equipment (MDD)

The Medical Devices Directive 93/42/EEC defines safety and performance requirements for medical equipment sold in the European Union. The requirements apply to both products and manufacturers, generally to all medical devices not covered by the Active Implantable Medical Devices Directive or the IVD Directive (In Vitro Diagnostics).

In order to obtain medical device approval in the EU, medical devices must be correctly classified. The Medical Device Directive defines products into different classes, based on risk and intended use, which determine the relevant conformity assessment procedure in Annex IX. For products classified with medium to high degree of risk (class Is, Im, IIa, IIb and III) the Medical Device Directive requires a conformity assessment procedure involving a notified body.

The Medical Equipment Directive includes products (e.g. instruments, appliances, equipment, materials) used for the diagnosis, prevention, treatment or alleviation of disease, injury, disability or pregnancy. It also includes products used for examination, replacement or alteration of the anatomy, such as implants.

The directive does not include medicines or products used in connection with out-of-body diagnosis (e.g. blood tests and similar tests).

Medical equipment is divided into different classes based on the product's risk profile. The classification rules are based on conditions related to how long the equipment is in contact with the patient, how innovative the equipment is, which part of the body is affected by the equipment and whether it is an active equipment.

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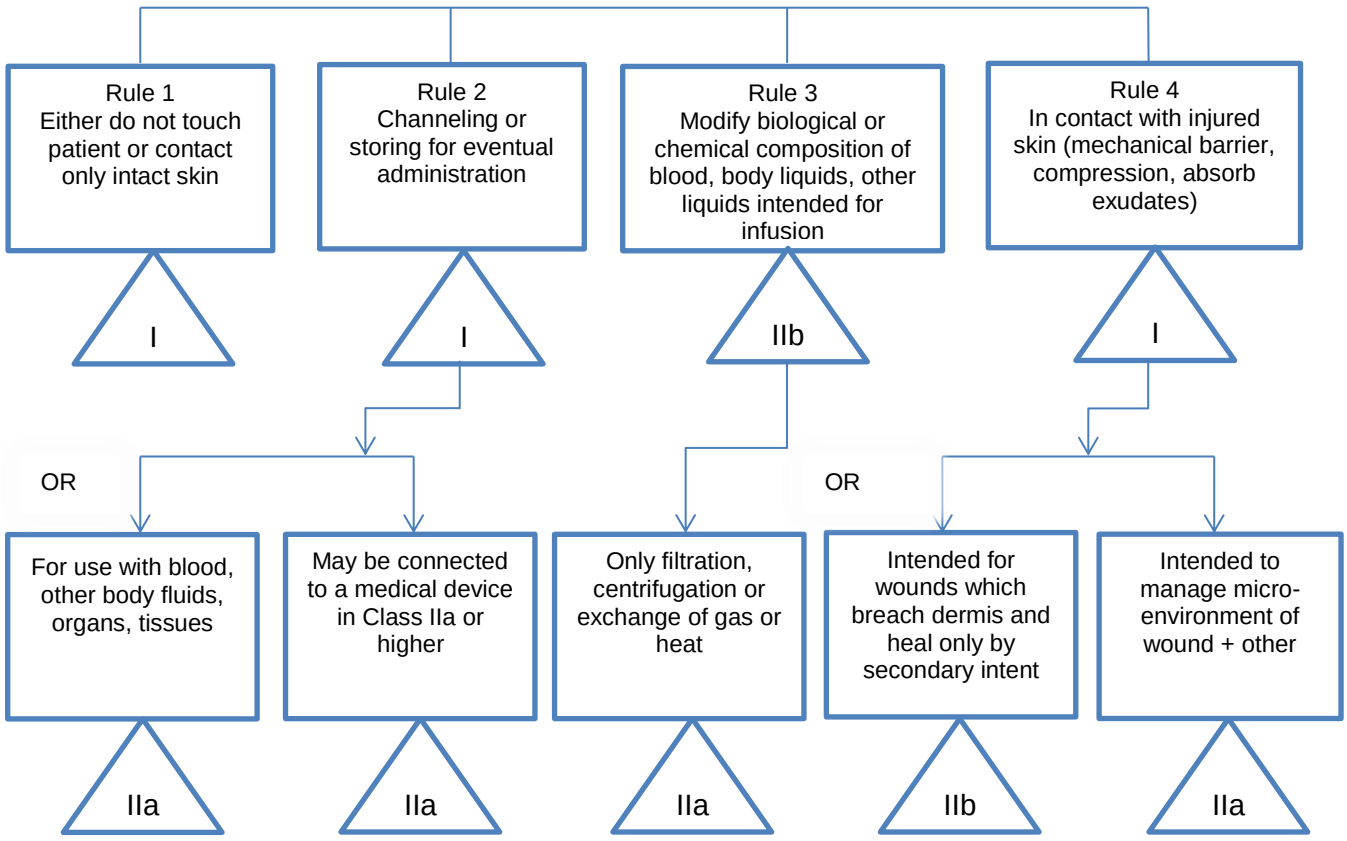
The table below shows some examples of equipment within the different risk classes.

Risk classe	Example of products
Class I	Products that are not in contact with the patient or which are only in contact with intact skin. E.g. stethoscopes, glasses, products for stabilizing body parts, hospital beds, wheelchairs etc.
Class I Steril	Sterile patches and bandages, sterile syringes without needle, sterile examination gloves
ClassI Measurement	Analogue thermometers, analogue blood pressure gauges, measuring kits
Class IIa	Needle, contact lenses, sterile surgical equipment such as scalpels, tweezers, scissors, cases, drills, hearing aids, ultrasound devices, MRI, ECG
Class IIb	Surgical implants such as orthopedic nails, plates and screws, respirators, incubators, defibrillators, surgical laser, X-ray dispensers, infusion pumps
Class III	Total hip and knee grafts, absorbable sutures, cardiac prostheses, stents with medication, cardiovascular stents and catheters.

Non invasive devices



Rule 2 applies to hospital systems with gas installation.

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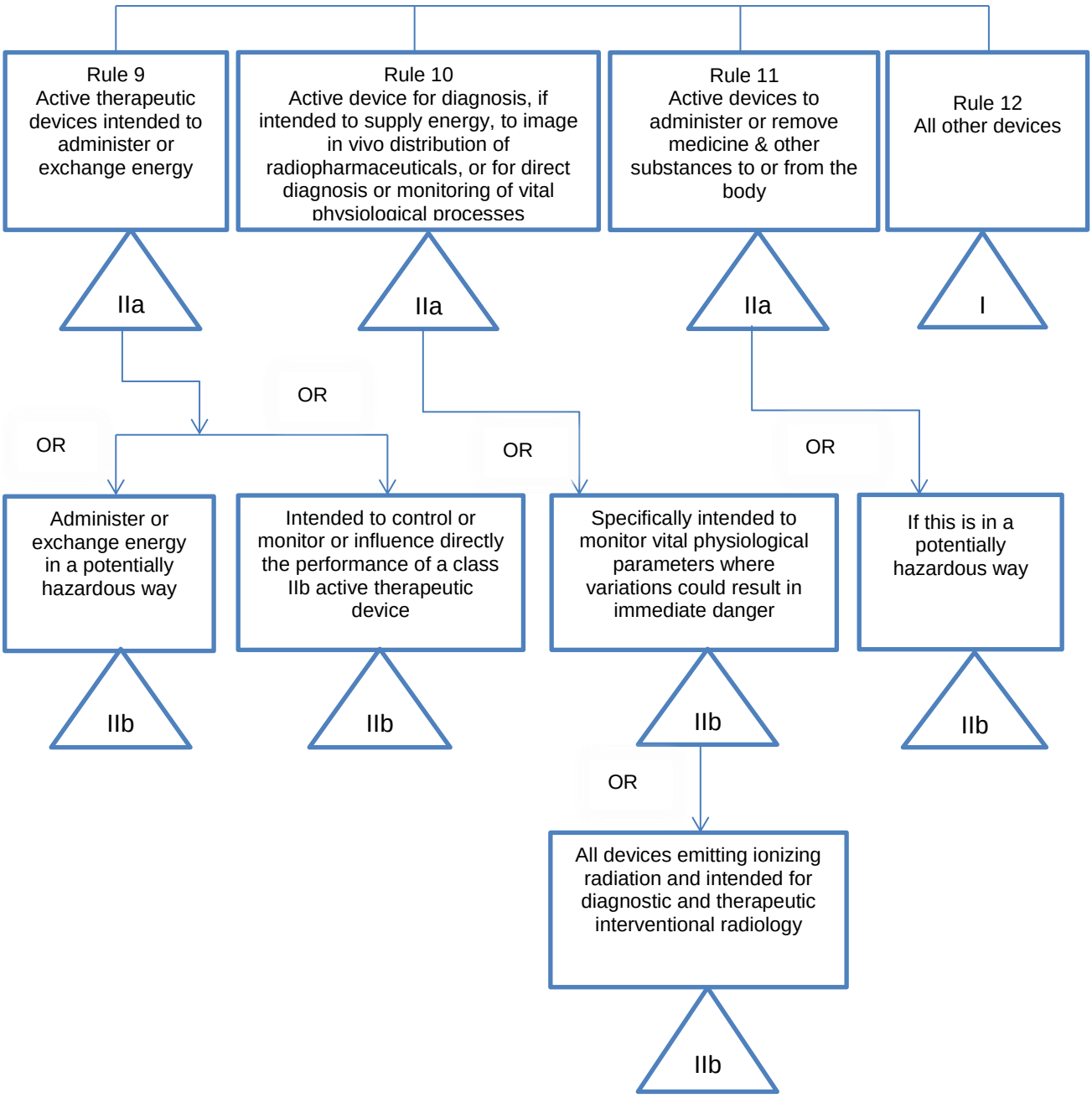
Active Devices



Rule 11 applies to hospital systems with gas installation and having ejector sewage built-in.

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Risk classification

Risk classification of the product is described in. MDD 93/42 / EEC Medical Device Directive; Annex IX. Meddev 2.4 / 1 rev 9.0

For Class I products, the manufacturer may make a self-declaration, Confirms compliance with the Medicines Directive. Requirements for documentation, risk assessment and Post Market Clinical Follow-up apply to Class I as for higher classes. For class I products there are no requirements for the use of technical control bodies (Notified Body). For Class II products, it requires Notified Body.

For Class I Sterile / Measurement, Classes IIa, IIb and III, it is required to use a technical inspection body to assess compliance with the requirements of the Directive.

The manufacturer chooses a self-assessment procedure after determining the risk class of the medical device.

Medical supply units are classified as medical devices and must meet the requirements of the Medicines Directive, MDD 93/42 EEC. How the products are classified according to what the panels contain.

Definition of medical devices is described in the 93/42 / EEC Medical Device Directive; Article I. and Meddev 2.1 Scope, field of application, definition.

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Classification of bead head units:

Medical supply units that contain only electrical installation are classified as Class I products.

Medical supply units that contain electrical installation and gas installation (medical gases) are classified as Class IIa products.

Medical supply units that contain electrical installation and gas installation (medical gases). Monitoring, regulating or controlling medical gases is classified as Class IIb product. E.g. panels with built-in suction injector.

Maxeta's Medical supply units are classified Classes IIa and IIb. Certified by Notofied Body: Presafe NB 2460. Our products CE are marked CE 2460.

Current standard for medical supply units

The directive contains its own requirements regarding electromagnetic compatibility (EMC) and electrical safety, and equipment containing electronics must meet these requirements as part of the MDD certification.

“ Technical” Standard ISO11197: 2009/12 applies for medical supply units/bed head units. Our product are type approved by Nemko according to this standard.

Demand in ISO 11197: 2009/12 for risk management control. This is according to EN 14971.

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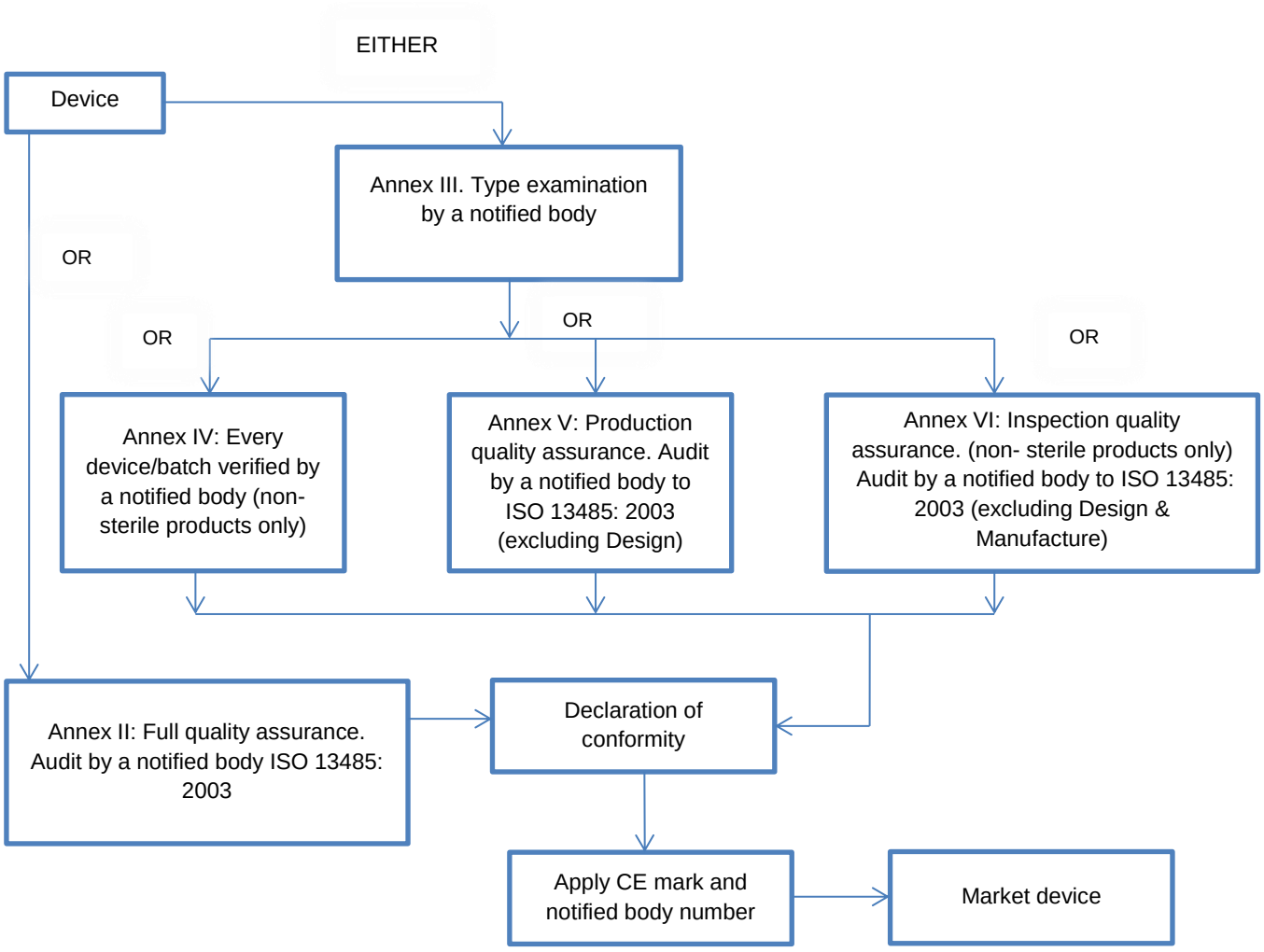
Route to Compliance

There are several alternative routes that can be used to CE mark a product. Which route you choose is up to the manufacturer. There are not many real choices for medical supply units, because the products are ordered according to the customer's specifications. There is continuous development of new solutions and integrations. Alternative routes are often without design. If all medical supply units were identical, alternative route would be a possible choice rather than a "complete" EN13485 quality assurance system.

Maxeta is EN13485: 2012 certified by Presafe. Our certification includes design, production, installation, sales and service.

Class IIB medical devices- CE marking routes



Flow chart for the conformity assessment procedure provided for in Directive 93/42 EEC on medical devices.

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Notified Body

There are several alternative Notified Body appointed by the Norwegian authorities for medical devices. In Norway, DNV, Presafe). Sweden, INTERTEK SEMKO AB. Finland VTT Expert Services Oy.

If the supplier are certified according to ISO 13485, the requirements for the quality system in the directive will also be met.

Maxeta's certifications related to hospital systems

MDD 93/42 EEC. Medicinal Products Directive. Certificate No. EU1404401

ISO11197 Standard for Medical Supply Devices Certificate No. P13217431

EN 13485 Quality assurance system for medical devices. Certificate No. NO-908256

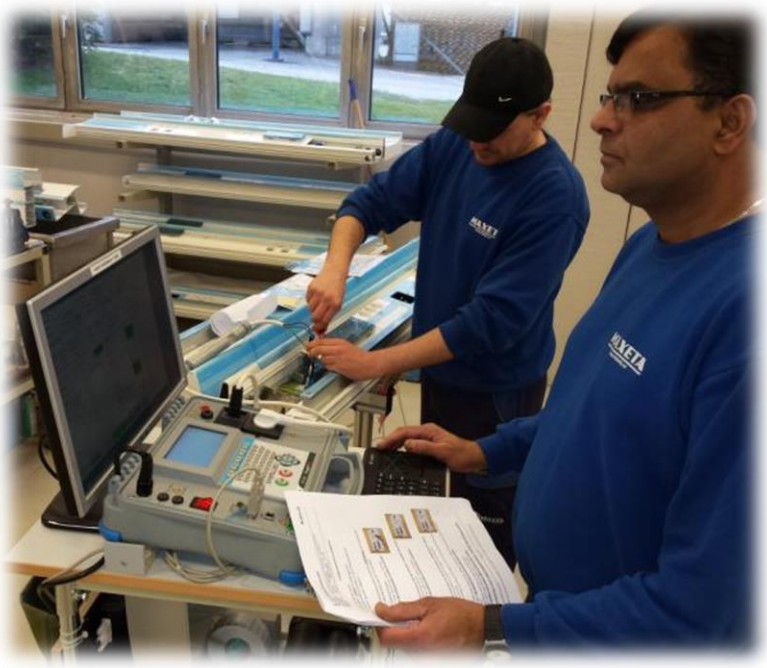
ISO 9001 Quality Management System. Certificate No. NO-800149

Post Market Clinical Follow up

One of the requirements in EN 13485. The manufacturer should proactively detect any serious problems with the product that may affect the patient's health and safety. We are continuously working on improving our products and are grateful for all good input.

Why Maxeta

Maxeta is the only Norwegian manufacturer of medical supply units. We have more than 20 years of experience. Our products are developed and manufactured in Skien by skilled employees. Maxeta provides solutions for nursing home and hospitals.



Route to CE marking

Step by step	References to the MDD 93/42 EEC Directive
Is this a medical device?	Article I
Classification (risk class)?	Article I IX
Compliance route	Article II
Basic requirements for the medical device?	Attachments I
Technical documentation	Attachments VII. *Recommendation-NB-MED-R2_5_1-5_rev4*
Surveillance	Attachments VII
Evaluation conducted by Notified Body	Attachments II-VI
Clinical evaluation	Attachments X
Product realization description of product, marking	Attachments I 13.3, Artikkel 14
Declaration of conformity	Attachments VII
CE marking	Article 17
Registration with health authorities	Article 14

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Registration, health authorities

Registrerte organisasjoner generelt medisinsk utstyr detaljer

Organisasjon registreringsnr: NO864425402/0811

Organisasjon status:	**Produsent**		
Navn:	**Maxeta AS**	Navn:	
Adresse:	**Amtmand Aallsgate 89, Skien, 3717, NORGE**	Adresse:	
Kontaktperson:	**Mr Rune Olsen**	Kontaktperson:	
Telefon nr:	**35 91 40 26**	Telefon nr:	
Faks nr:	**35 91 40 10**	Faks nr:	
E-post:	**rune.olsen@maxeta.no**	E-post:	
Størrelse:			

Risikoklasse IIb

Utstyr, registrerings nummer	*Gruppekode*	*Generisk kode og beskrivelse*	*Navn på produkt*	*Måleft teknis*
NO864425402/0811-53567	Elektro/mekanisk medisinsk utstyr	[36810] General utility supply system, wall-mounted	General utility supply system	n/a
NO864425402/0811-53568	Elektro/mekanisk medisinsk utstyr	[36810] General utility supply system, wall-mounted	General utility supply system	n/a
NO864425402/0811-53569	Elektro/mekanisk medisinsk utstyr	[36810] General utility supply system, wall-mounted	General utility supply system	n/a
NO864425402/0811-53570	Elektro/mekanisk medisinsk utstyr	[36810] General utility supply system, wall-mounted	General utility supply system	n/a
NO864425402/0811-53571	Elektro/mekanisk medisinsk utstyr	[36810] General utility supply system, wall-mounted	General utility supply system	n/a
NO864425402/0811-53572	Elektro/mekanisk medisinsk utstyr	[36810] General utility supply system, wall-mounted	General utility supply system	n/a

Final inspection of Maxeta's products

Test routine Florence KP-003

Final inspection for Florence bed head units. In the event of rebuilding or modification, production procedures must be followed, and final inspection procedures carried out in the same way as during production in order for the product to comply with the requirements of the MDD Directive.

Medical supply unit or regular electricity. Installation?

This is related to intended use. If the bed head unit are made for “supplying” medical devices, it is defined as a medical supply unit. In this case, ISO 11197 applies, standard for Medical Supply units which is covered by the MDD Directive.

Intended use of Florence bed head units:

Florence bed head units are medical supply units designed for permanent wall mounting in treatment and patient rooms. The panels distribute electrical power, low-voltage installations (mainly tele / data) and nurse call alarms as well as medical gases. The bed head units are for permanent use with a life of approx. 25 years.

In ISO 11197 a medical supply unit is described:

201.3.103
MEDICAL SUPPLY UNIT

permanently installed ME EQUIPMENT intended to supply electric power, communication means (telephone, call systems, etc.), data transmission, lighting, and/or MEDICAL GASES and/or liquids, an ANAESTHETIC GAS SCAVENGING SYSTEM and/or a PLUME EVACUATION SYSTEM to medical areas of a healthcare facility

Note 1 to entry: MEDICAL SUPPLY UNITS can include ME EQUIPMENT or ME SYSTEMS or parts thereof. MEDICAL SUPPLY UNITS can also consist of modular sections for electrical supply, lighting for therapy or illumination, communication, supply of MEDICAL GASES and liquids, PLUME EVACUATION SYSTEMS and ANAESTHETIC GAS SCAVENGING SYSTEMS. Some typical examples of MEDICAL SUPPLY UNITS are bed head service modules, ceiling pendants, beams, booms, columns, pillars, cabinetry, concealed COMPARTMENTS on or in a wall and prefabricated walls.

Note 2 to entry: Examples of configurations are given in Figures 201.103, 201.104 and 201.105.

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Definitions in NEK 400-7-710 (HD384, IEC 60364) Medical Areas:

Areas intended for examination, treatment, monitoring and care of patients.

Patient:
Living person or animal undergoing medical, surgical or dental examination or treatment.

Group 0
Area not provided for use as patient part. Any failure of the power supply will not endanger life and health.
Group 1
Area to be used for the treatment of a patient, where power interruptions will not endanger life and health.

Group 2
Area used for vital treatment of patients where interruptions can endanger life and health.

Description:

Bead head units must be CE marked according to the MDD 93/42 EEC Medicines Directive, must be produced in accordance with the current standard for medical supplies ISO 11197 and must satisfy the purity requirements for gas installations, described in SIS HB 370 (Norway and Sweden).

Checklist for what is usually installed in a bed head unit:

- Unit type size / design
- Number of power outlets and circuits. LED indicator in group 2 rooms (Norway)
- Number of low power outlets, tele data, nurse call
- Number of boxes for nurse call signals, usually 1 or 2 boxes
- Number of boxes for other equipment, for example light control
- Number of medical earthing points
- USB charger
- Integrated uplight, T5, LED Color K
- Integrated reading light, T5, LED color K, describe light control
- External reading lights, Luxo Carelight / Derungs, clamp for rail mounting?
- Fuses integrated
- Medical rail, 10x25 or 10x30. Integrated in panel or mounted on wall. Length?
- Number of gas outlets and types

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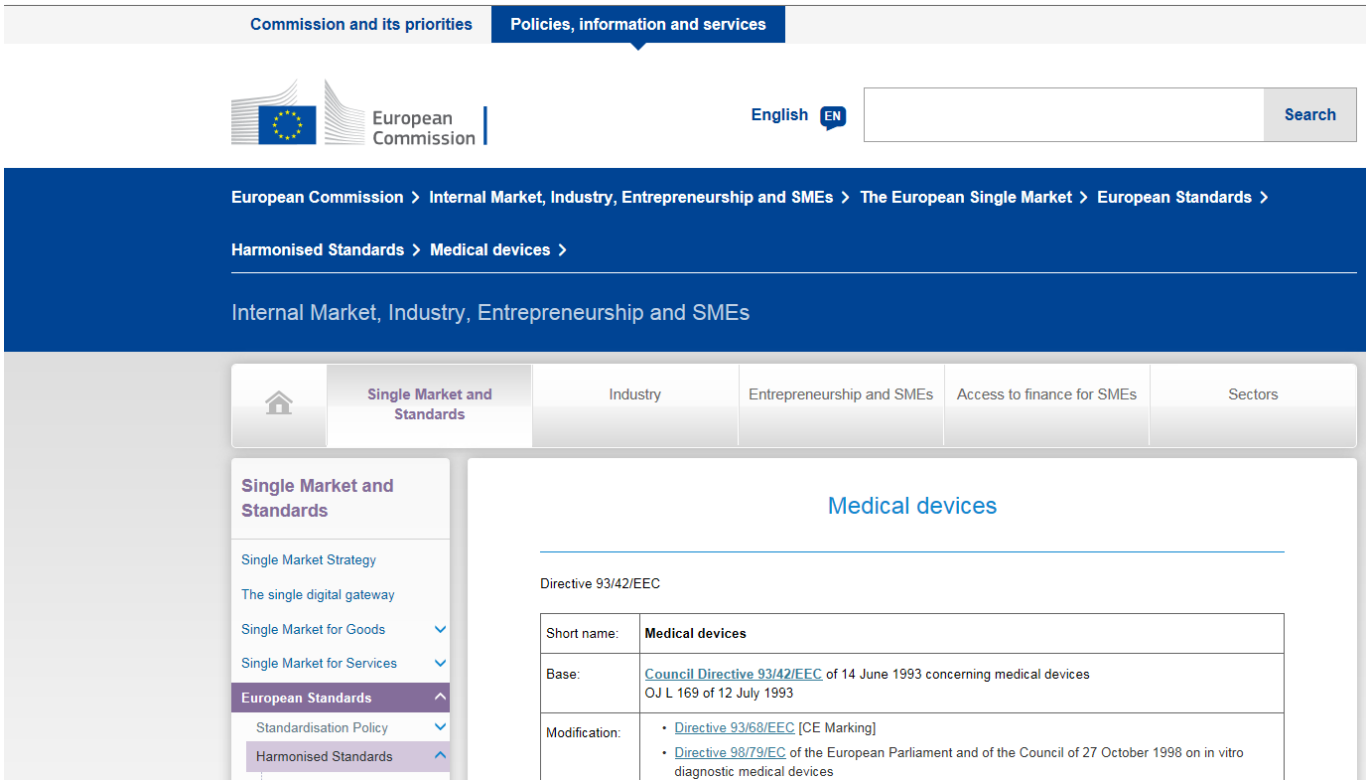
Harmonised Standards

Directive 93/42/EEC

https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/medical-devices_en



CEN	EN ISO 11197:2009 Medical supply units (ISO 11197:2004)	02/12/2009	EN ISO 11197:2004 Note 2.1	21/03/2010

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