

waveguard™ original

EEG cap & accessories



User Guide

Rx Only. Caution: US Federal Law restricts this device to sale by or on the order of a physician.

User Guide for the **waveguard™** original EEG cap

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The **waveguard** EEG cap is a medical device of CE class I according to the Regulation (EU) 2017/745 (MDR), and also according to 2011/65/EU (RoHS).

In the USA, **waveguard** EEG cap is a class II device according to the CFR, FDA 510(k) No. K110223.

In Canada, certain cap types are registered as medical device class II according to the MDR under MDL number 88779.

For product registrations in other countries send your inquiry to sales@eemagine.com.



Important Notice

Every care has been taken to ensure the accuracy of the information in this document. However, we assume no responsibility for errors, inaccuracies, or omissions that may appear in this document.

We reserve the right to change the product without further notice to improve reliability, function or design. This document is provided without warranty of any kind, implied or expressed, including fitness for a particular purpose.

Please read this manual carefully before using a **waveguard** cap.

The cleaning and disinfecting procedures as described aim at a most careful cap maintenance. However, eemagine GmbH cannot control whether these procedures are properly followed, nor can we assess the quality of third-party cleaning products. As a consequence, eemagine GmbH does not assume any liability for the cleanliness of caps and the fitness of caps for EEG recordings after cleaning. In particular, eemagine GmbH does not assume any liability for infections that may be caused by using EEG caps previously washed and/or disinfected by the user.

In addition to this information, please always follow the regulations that apply locally in your country and hospital or institute. Contact your distributor if you are in doubt about what regulations apply and how to meet them.

Please contact your distributor in case of a defective cap or other required support. Do not try yourself to repair caps yourself if there is still warranty on the cap. If you do so, the warranty will be void. Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of your country.

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Contents

1	SAFETY INFORMATION	4
1.1	Intended use	4
1.2	Contra-indications	4
1.3	Side effects.....	4
2	IMPORTANT WARNINGS.....	5
3	WAVEGUARD CAPS	6
3.1	Description of the cap.....	6
3.2	Cap accessories	6
3.2.1	Adapters	6
4	APPLICATION OF THE WAVEGUARD CAP	8
4.1	Preparations and cap positioning	8
4.1.1	Neonatal caps	8
4.2	Fixation of the cap	9
4.2.1	Neonatal caps	9
4.3	Connecting the cap with the EEG recording system.....	9
4.4	Gel usage	9
4.4.1	Neonatal caps	10
4.5	Connecting loose-hanging droplead electrodes.....	10
4.6	Replace a defect electrode with a waveguard Fast-Fix	10
5	CLEANING AND HANDLING OF CAPS	12
5.1	DOs and DON'Ts for Washing.....	12
5.2	Drying	13
5.3	Disinfecting caps.....	13
5.4	Usage & Environmental conditions.....	14
6	OTHER IMPORTANT INFORMATION	15
6.1	Waste disposal	15
6.2	Warranty and Support	15
6.3	Available cap sizes	16
6.4	Lifetime of caps	16
	APPENDIX: EU DECLARATION OF CONFORMITY	17

1 Safety information

1.1 Intended use

waveguard EEG caps are intended for recording of electroencephalographic (EEG) signals, including event-related potentials (ERP) and evoked potentials (EP) on subjects or patients with intact scalp in combination with medical-grade EEG recording equipment (CE class IIa certified inside the European Union; class II device according to FDA regulations for USA).

The cap must be dry and clean when used. The application of caps on subjects or patients should only be carried out by medically trained personnel (EEG technician). The technician must remain present during the entire recording session to prevent patient risks such as strangulation. Special infection control requirements may apply.

Regulatory information for users in the USA:

This is an EEG electrode set intended for routine clinical settings where rapid placement of large number of EEG electrodes is desired.

Some special type caps: e.g., MRI-compatible **waveguard** caps, are for research only in USA, and may need special washing procedures and/or precautionary measures to make sure that the cap is not magnetically contaminated.

The **waveguard** family are considered Medical Devices, denoted with the MD symbol in the device label.



1.2 Contra-indications

The caps should not be used on patients with skin injuries or problems such as blisters, burns, wounds from operation or other superficial wounds or transmissible diseases, such as – but not limited to – hepatitis, human immunodeficiency virus (HIV) or Creutzfeldt-Jacob disease.



Do not use the cap in a Magnetic Resonance Imaging (MRI) scanner or in any other high-intensity electromagnetic field radiation environment unless the type of the cap expressly states the compatibility with such a device.

In the event of defibrillation, disconnect the cap and/or electrodes from the EEG recording equipment first.

1.3 Side effects

No side effects are known if properly applied. Please apply the correct size of the cap. Keep in mind that a too small cap may cause headache. Slight red marks on the exposed skin (e.g. at the forehead) due to contact pressure are a regular effect of wearing the cap and disappear within short time.



2 Important Warnings

- **Before the first use, make sure that the cap is properly disinfected and clean.**
- Do not use incompatible electrode materials like platinum or stainless steel in one recording.
- Do not use hard brushes or any other hard materials (in particular no metal tools such as screw drivers) to clean electrodes.
- Apply always the correct size of cap (related to head circumference).
- Make sure that the cap is completely dry before use.
- Make sure to use the appropriate amount of gel for each electrode; too much gel can lead to invalid signals.
- Do not clean the cap using an ultrasonic cleaning device.
- Do not keep the cap submerged in water for prolonged periods of time (maximum one to two hours).
- Do not expose the cap to hot environments over 50° Celsius (or short rinsing at 60° Celsius). The cap fabrics as well as the wiring do not withstand higher temperatures. Hot-air drying may significantly reduce the lifetime of the cap.
- Do not try to wring or squeeze the cap! We recommend to gently dab the cap fabric using a towel, or to hold the cap between two towels for drying.
- Do not use any autoclaving procedure on the cap.
- Make sure that the cap connectors always remain dry.
- Please dry the cap ideally in an upside-down position, with the cable being placed higher than the wet cap, in order to prevent adapter and tubing to be contaminated with water.
- Always disconnect caps holding the connector housing. Never drag at the cable! Note that dragged-out cables are not covered by the cap warranty.

- The sintered Ag/AgCl electrode elements do not need any rechlorification.

Additional note for special MEG type caps (magnetoencephalography):

- You must take every precautionary measure to make sure that the cap is not magnetically contaminated.
- The cap may require a special washing procedure.

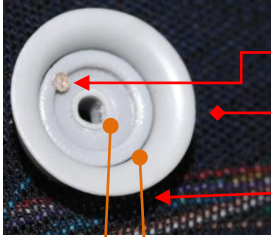
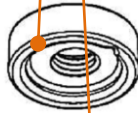
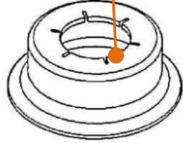
Additional notes for special neonatal type caps - special warnings apply:

- When used for neonates inside an incubator, for a correct application, use the correct size!
- You must be extra careful with the skin preparation and gelling procedures, and may consider using extra-thick gel that allows pre-gelling the cap prior to placing the cap on the baby's head.
- Do not use a hard comb for brushing the hair of the patient.
- Prevent the baby from laying on an electrode for prolonged time.
- Make sure to check the baby's head and condition of the skin on a regular basis.
- The cap may require a special washing procedure.

3 Waveguard caps

3.1 Description of the cap

We provide a short description of the individual parts here, which helps in communicating on details or identifying problems when using the cap.

	Electrode element as seen from inside of cap “Pin” Ag/AgCl (sintered silver/silver chloride) Inside “Lining” fabric (same material as outside fabric) “Wiring” (hidden between outside fabric and lining)
	“Electrode-housing” with electrode element and cable
	“Flex-ring” holds the gel and provides contact with skin
	“Top screw” with gel insertion hole
	“Label” (between outside fabric and top screw)

3.2 Cap accessories

3.2.1 Adapters

The waveguard EEG cap comes with different types of connectors. Shielded caps are equipped with *high-density* connectors, whereas unshielded caps usually come with Sub-D connectors. Caps with Sub-D connectors (one per set of 32 channels) can usually be directly plugged into the EEG amplifier. If *Touch-Proof* single inputs (DIN 42802) are to be used, an adapter from Sub-D to single *Touch-Proof* leads can be provided.

For shielded waveguard caps in combination with certain ANT EEG recording systems, an adapter is purchased with the amplifier (per set of 32 electrodes, maybe different for some caps with fewer electrodes). Such adapters are historically named “Electrode-Board-Adaptor” or EBA. This adapter must be attached to your amplifier according to the numbered labels as available on the wires. For the first 32 channels, this is straightforward, matching the numbers on the amplifier and adapter. If you have an amplifier with more channels, the second adapter will attach to channels 33-64, the third adapter will be inserted to channels 65-96, and the fourth one to channels 97-128.



The exact configuration may vary depending on the layout of your amplifier system (e.g., for cascaded setup of two 72-channel amplifiers, where the third adapter attaches to channels 73-104).

The black connector (with GND label) of the first adapter should be attached to the Patient Ground (GND) of the EEG amplifier. The GND position can differ per cap type.

It may be beneficial for improved suppression of common-mode signals to use a ground electrode external to the cap (esp. with high density caps, to prevent the occurrence of gel bridges). You may make use of a self-adhesive electrode, compatible with the Ag/AgCl electrodes in the cap, such as indicated in the picture on the right, and apply this e.g. on the collar bone.



4 Application of the waveguard cap

- ✓ Apply always the correct size of cap (related to head circumference).
- ✓ Make sure that the cap is completely dry before use.

4.1 Preparations and cap positioning

Gently pull the cap over the patient's head, starting at the forehead. Pull on towards the back of the head while carefully placing the cap symmetrically.

To position the electrodes correctly, find the reference point halfway the distance of Nasion to Inion and halfway the distance between the two pre-auricular points. This is where electrode **Cz** is located. The frontal electrodes **Fp1**, **Fpz** and **Fp2** should be positioned at 10% of the Nasion-Inion distance, which is a few centimetres above the eyebrows. Likewise, positions **O1**, **Oz** and **O2** should be 10% above the Inion.

Using the correct size of cap (related to head circumference) is important for achieving a good positioning accuracy. Stretching a cap over a head that is too big for it may cause excessive wear of the fabric and also places the electrodes superior to their actual locations. Please refer to the size table and chart in this user guide. Head circumference is measured over the most prominent part on the back of the head (occiput) and just above the eyebrows (supra-orbital ridges).

Try to position the cap correctly in one go, without further shifting the cap. This may prevent slow drifts in the EEG because displaced hair tends to shift back. You may ask the patient to hold the frontal electrodes in place while putting on the cap.

It is advantageous to comb the hair using a relatively hard hairbrush before applying the cap. You can either assist the patient with the brushing, or have the person do this him/herself. The brushing removes some dead skin particles/dandruff, resulting in lower electrode impedances.



4.1.1 Neonatal caps

- ✗ Do **not** use a hard comb for brushing the hair of the patient.
- ✓ Check carefully that the patient is not laying on an electrode for prolonged time, thereby introducing pressure points on the babies' scalp with risk of oedema. You must check the skin condition of the patient frequently at a regular interval.

In neonatal caps typically, available electrodes are F3/4, C3/4 or P3/4 etc... Make sure that at least two electrodes are correctly aligned with the physiological position before applying the cap on the patient.

4.2 Fixation of the cap



The standard fixation of the cap is achieved with a chin band clipped to the left and right side below the ears. An alternative solution is provided as chin strap that is stretched over the chin and fixated with Velcro underneath the flaps of fabric that hold the fixation clips.

For users having problems with chin fixation, we provide a chest belt, which is clipped to the left and right side below the ears.

4.2.1 Neonatal caps

Take care that the clips or cap straps are not tied in a knot and not fixated in any other way, in order to prevent any risk of strangulation.

4.3 Connecting the cap with the EEG recording system

- ✗ Do not use incompatible electrode materials like platinum or stainless steel in one recording.
- ✗ Never drag at the cable! Note that dragged-out cables are not covered by the cap warranty.
- ✓ Always disconnect caps holding the connector housing.

The cap comes with a connector for every set of 32 or less electrodes. Make sure that properly matching connectors are used. Cable outlets at the cap side are numbered if more than one connector is present. When using more than 32 channels, double-check that the numbering is in accordance with the channel inputs at the EEG recording hardware (or adapters, if used). When disconnecting a cap, take special care not to drag at the cables but hold the connector housing tightly to remove the plug.

With certain *high-density* connectors (“Hirose”), side latches have to be gently pressed to separate the two pieces.

4.4 Gel usage

We recommend using *OneStep* conductive gel. *You should use only conductive gel that is CE certified (Europe) or FDA approved (USA) for medical use.*

Apply the gel using dedicated syringes with blunt needles for easier insertion through the hole of the electrodes. Make sure to use the appropriate amount of gel for each electrode; too much gel can lead to invalid signals.

First bring in the blunt needle down through the hole and touch the scalp. Put some pressure on the syringe and inject gel while slowly taking out the syringe to form a gel bridge between scalp and electrode. Typically you need ca. 10 ml of gel for 32 electrodes. Be careful not to damage the skin with the needle, especially on the temples and on the mastoids: often the skin is more delicate at these positions.

You should never scratch the skin but may use the needle to move away some hair (gently move in circles) before inserting gel if necessary.



When using the cap for long time, i.e. more than 4 hours, you may have to apply additional gel to some contacts, you must check the skin condition of the patient frequently at a regular interval. Be careful when you remove the cap after long-time use since gel remnants may firmly attach the electrode flex-rings to the skin, and may cause flex-rings to come loose from the electrode-housing. To facilitate removing the cap, apply lukewarm water to the electrodes or to the cap and let the gel soak up the water for a minute.

4.4.1 Neonatal caps

For neonates use soft plastic syringe needles instead to prevent any hazards of accidental scratching.

4.5 Connecting loose-hanging droplead electrodes

Some cap types are equipped with electrodes that hang loose, i.e. extend from the cap's edge, so-called dropleads. This can for example be the GND electrode or a special EOG electrode. This type of electrode can best be fixated by using a double-sided ring-shaped sticker as shown in the example below.



4.6 Replace a defect electrode with a waveguard Fast-Fix

In case of a defect lead, e.g. due to a broken wire, you can quickly patch the connection using the **waveguard** Fast-Fix electrode. The sensor inside the electrode is made of the same sintered Ag/AgCl material as in the electrodes on the cap.

Note that the concept of a replacement electrode only works if your cap is connected with an adapter.

1. Look up the channel number of the broken channel.
The channel number is typically displayed in the



impedance view of the EEG recording software.

2. On the amplifier input panel, take out the connector of the adapter that is associated with the channel number.
3. Plug the connector of the Fast-Fix electrode into this input.
4. Gently place the Fast-Fix electrode in the gel insertion hole of the respective electrode on the cap (after having inserting sufficient gel). The pin then immediately provides a proper connection for that particular electrode position. Be careful not to push the Fast-Fix too tight as this may break the top screw.

5 Cleaning and handling of caps

The sintered Ag/AgCl electrode elements do not need any rechlorification.

5.1 DOs and DON'Ts for Washing

- ✗ Do not clean the cap using an ultrasonic cleaning device.
- ✗ Do not keep the cap submerged in water for prolonged periods of time (maximum one to two hours).
- ✗ Do not use any hard mechanical tool for cleaning of the electrodes. The electrode elements may break with force.
- ✗ Do not use any autoclaving procedure on the cap.
- ✓ Make sure that the **cap connectors always remain dry**.

We strongly recommend rinsing the cap with lukewarm water immediately after use.

You can do this at a regular sink; best is to use a **showerhead** attached to the faucet. Hold the cap inside-out with one hand, and rinse the gel out of the electrode cups with a firm spray of water.



The best way to clean the electrodes is to use an **oral douche** (or water-pik) machine such as available for dental cleaning. The focused water spray is perfect for getting out the gel and cleans the electrode elements completely. A regular shower head can be used to rinse off remaining gel.

You should also rinse clean the cap fabric!

Your next patient will appreciate a clean cap! Use only non-detergent, non-perfumed, soft soap.



Keep the cable and connectors away from the water when cleaning the cap. Avoid any moisture near the connectors in order to completely prevent possible short-circuits or corrosion. In the event that you need to clean the connectors, use a cotton stick slightly damp with alcohol (do *not* use this on the electrodes).



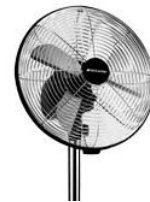
5.2 Drying

✗ **Do not expose the cap to hot environments over 50° Celsius** (or short rinsing at 60° Celsius). The cap fabrics as well as the wiring do not withstand higher temperatures. Hot-air drying may significantly reduce the lifetime of the cap.

✗ **Do not try to wring or squeeze the cap!** We recommend to gently dab the cap fabric using a towel, or to hold the cap between two towels for drying.

✓ **Please dry the cap ideally in an upside down position**, with the cable being placed higher than the wet cap, in order to prevent adapter and tubing to be contaminated with water.

The cap must be completely dry before next use. Do not use a hot hair dryer to dry the cap. A solution to shorter drying time is to use a cooling (table) fan. In the cool air stream, drying is quick and safe, within approximately 20 minutes.



5.3 Disinfecting caps



Make sure that the cap is adequately cleaned prior to disinfecting. Examples of disinfectant solutions that are known to work satisfactory are Cidex OPA (by Advanced Sterilization Products) or Metricide, Cavicide (by Metrex), Pursept AF (by Schülke & Mayr), Sekusept activ (by Ecolab) or Korsolex Extra (by BODE Chemie).

You must follow the disinfectant's instructions for use and especially rinse the cap properly. Plastic parts, such as labels, flex-rings and the fabric, may bleach slightly. This is normal and does not interfere with the normal usage of the cap.

- ! The use of disinfectant may reduce lifetime of the caps.
- ! Alcohol is not an adequate solution for disinfecting electrodes.
- ! Hydrogen peroxide solutions should not be used.
- ! **Please make sure that local and hospital regulations for cleaning are always followed!**

General guidelines for disinfection are available through the following links:

- CDC (USA) - www.cdc.gov/infectioncontrol/guidelines/disinfection/
- Robert Koch Institute - doi.org/10.1007/s00103-017-2634-6
- World Health Organisation - www.who.int/infection-prevention/publications/decontamination/

User Guide for the waveguard™ original EEG cap

An example of disinfectant solutions that are known to work satisfactorily is Korsolex Extra (by BODE Chemie, Germany). You must follow the disinfectant instructions for use and especially rinse the cap properly afterwards. The list below is an example of the procedure.

Disinfection solution

all quantities are stated for Korsolex Extra only. For other providers please refer to their guidelines.

1. Mix 4% of the disinfectant liquid with 96% distilled water in a bucket.
2. Wear protection gloves.
3. Completely submerge the cap in the liquid. Be careful to not wet the connectors.
4. Pull out the cap and submerge it again in the solution. Repeat this procedure at least 5 times.
5. Leave the cap submerged in the disinfectant for about 15 minutes.
6. Remove the cap from the bucket and rinse the cap with distilled water.

✓ Make sure the cap is adequately cleaned prior to disinfecting

✗ Do not keep the cap submerged in any disinfection liquid for prolonged periods of time.

5.4 Usage & Environmental conditions

Parameter	Description	Unit	nom	min	max
Period of use	Routine EEG recording	h	1	NA	24
Operating temperature		°C	25	5	35
Cleaning temperature (defined procedure)	max. 1 minute, for very short rinsing up to 60°C is acceptable (<10 seconds)	°C	25	20	50
Storage temperature		°C	NA	5	40
Transport temperature		°C	NA	0	40
Humidity		%	NA	15	70
Atmospheric pressure	(altitude <2000m)	kPa	NA	80	106
Max. Pollution degree	a micro-environment where only non-conductive pollution occurs except that occasionally a temporary conductivity caused by condensation is to be expected.	NA	NA	NA	NA

6 Other important information

Inspect the cap carefully in regular intervals, preferably prior to every use, for gel remnants in the electrodes, visible damage to fabric (outside and inner lining) and the cable protection, and the cable bundles that extend from the cap, and check the connector(s) for defects of the plastic housing, broken or corroded electrodes.

6.1 Waste disposal

Caps must be disposed of as electronic waste in accordance with local legal regulations.



WARNING: Before you dispose of any item, you must ensure that all materials that have been in contact with the patient are not contaminated. You may have to thoroughly clean and sterilize before disposal.

6.2 Warranty and Support

The **waveguard** cap is made of high-quality materials:

electrode elements	Sintered Ag/AgCl (pure 99.99% silver)
cap fabric	83% Polyester, 17% Elastan (spandex)
electrode housing	Polyurethane (PUE)
flexible ring (inside of cap)	Medical grade silicone (withstands acid, oil, solvents)

All caps are carefully inspected before they leave the factory. A **waveguard** original cap is delivered with a limited warranty for the period of **12 months** after delivery, based on the condition that it was handled according to the indications for use described in this user guide. In summary, the limited warranty provides that each product will conform to its specification and will be free from defects in material and workmanship, including:

- Loose seams, holes in the cap fabric, e.g. caused by defects in the sewing process
- Breaking of electrode elements, if not caused by inadequate cleaning/handling
- Broken wires inside the cap, defective cable extending from cap to connector
- Defects inside the cap connector

For repair claims please contact your distributor to get detailed information or instructions for warranty and self-repair services. Warranty is excluded for damage caused by misuse of the cap and the examples:

- Broken/missing connector latches (high-density connectors only)
- Defects in the chin-strap/chin-band
- Broken/missing flex-rings
- Normal wear-and-tear of the electrode labels or other labels attached to the cap

Note: final judgement is taken by *eemagine GmbH* after having received the cap in question.

IMPORTANT: Caps returned to the manufacturer for repair – warranty or not – are sent back on the customer's account without inspection/repair if they are not thoroughly cleaned.

6.3 Available cap sizes

Caps with 128 or more electrodes are slightly less flexible than indicated.

Also see the size chart below for limitations on number of electrodes in a given size.

Some cap types may differ in allowed number of electrodes.

Order code	Sizes	Head circumference		Head circumference		Fabric color scheme			Number of electrodes in cap						
		Min. (cm)	Max. (cm)	Min. (in)	Max. (in)				4-8	21-24	32	43	64	128	256
CA-XXX.11	L Large	56	61	22	24	●	●	●	●	●	●	●	●	●	●
CA-XXX.10	M Medium	51	56	20	22	●	●	●	●	●	●	●	●	●	●
CA-XXX.09	S Small	47	51	18.5	20	●	●	●	●	●	●	●	●	●	--
CA-XXX.08	C Child	43	47	16.9	18.5	●	●	●	●	●	●	●	●	●	--
CA-XXX.07	I Infant	39	43	15.4	16.9	●	●	●	●	●	●	●	●	--	--
CA-XXX.06	B Baby	36	39	14.2	15.4	●	●	●	●	●	●	●	●	--	--
CA-XXX.05	N5 Neonatal	33	36	13	14.2	●	●	●	●	●	●	●	--	--	--
CA-XXX.04	N4 Neonatal	31	33	12.2	13	●	●	●	●	●	●	--	--	--	--
CA-XXX.03	N3 Neonatal	29	31	11.4	12.2	●	●	●	●	●	●	--	--	--	--
CA-XXX.02	N2 Neonatal	27	29	10.6	11.4	●	●	●	●	●	--	--	--	--	--
CA-XXX.01	N1 Neonatal	25	27	9.8	10.6	●	●	●	●	●	--	--	--	--	--

(Size indication serves as guideline only – optimal fit depends on head shape and hair style)

6.4 Lifetime of caps

How long a cap can be used with all electrodes intact and without compromising signal quality depends upon many factors. Careful handling and thorough cleaning are most important. The electrode sensors, the fabric along with all other parts and materials have been selected and designed such that more than 500 cycles of recording and cleaning can be reached.

Please do not hesitate to contact us in case you have suggestions how the quality of the caps as well as this user manual can be further improved.

Appendix: EU Declaration of Conformity

Hereby we declare in exclusive responsibility that below identified products fully comply with the regulations of the Medical Device Regulation (EU) 2017/745 (MDR) on medical devices.

To the best of our knowledge given the information provided by our suppliers, products are also in conformity with the Council Directive 2011/65/EU (RoHS) on the restriction of the use of certain hazardous substances in electrical and electronic equipment, as amended by Directive (EU) 2015/863. Products are not made with natural rubber latex, and do not contain BPA.

waveguard™ EEG cap and accessories

Electrode caps, adapters and leads for recording of EEG signals

The product family consists of devices that are classified according to MDR Annex VIII, rule 1, as **CE class I**, and meets the applicable *General Safety and Performance Requirements* of the MDR Annex I.

We apply the conformity assessment procedure in accordance with MDR Annex IX and issue this declaration of conformity as manufacturer.

Products are marked with



The applicable sections of the following standards have been used as a basis for the conformity:

- <IEC 60601-1:2005/A1:2012>
- <EN ISO 14971:2019>
- <EN ISO 10993-1:2009, EN ISO 10993-5:2009, EN ISO 10993-18:2009>
- <IEC 62366-1:2015>
- <EN ISO 15223:2021>

This declaration DOC-QA-0001 is valid for product codes **REF** as stated in the appended product list.

The corresponding *Global Medical Device Nomenclature* (GMDN) code is: 63131.

We are registered with HIBCC, with *Labeler Identification Code* (LIC): B195.

EUDAMED assigned our *Single Registration Number* (SRN): DE-MF-000005560.

The *notified body* involved in the assessment of our quality management system is:
<notified body name, address>.

Current certificate EN ISO 13485:2016 <registration information>.

Dated at Berlin, Germany, on the ____ day of _____ <2022>.

<CEO>

eemagine Medical Imaging Solutions GmbH

For the exact <information> in the above text, see the official, signed declaration DOC-QA-0001. The contents of similar conformity statements may be different in countries outside the European Union.