Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 077790 0060 Rev. 00

Manufacturer: **Covidien LLC**
15 Hampshire Street
Mansfield MA 02048
USA

Product Category(ies): **Oximetry and Capnography Monitor Systems Temperature Monitor Systems, Patient Warming Device Systems, Disposable Airway Management Devices, Tracheal Tubes, Tracheostomy Tubes, Speaking Valves, and Intubating Stylets, Ventilator Systems and Patient Interface Circuit Systems, EEG Monitoring Systems, Breathing Therapy and Humidification, Heated Inspiratory Line Humidifiers, Multi-patient Physiologic Monitoring System and Data Analytics Software, Gastrointestinal Measurement and Dilation System, Electrosurgical Diathermy System Electrode.**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II.
This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 72145607

Valid from: 2020-06-29
Valid until: 2024-05-26

Date, 2020-06-29

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...cation/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

Declaration, including the attached schedule, should be printed on form as used for a Declaration of Conformity per manufacturer's QMS (e.g. manufacturer's letterhead)

Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Covidien LLC
Manufacturer address and contact details	15 Hampshire St. Mansfield, MA 02048 USA Contact: rs.eudamedinquiries@medtronic.com
Single Registration Number (SRN) (if available)	US-MF-000028763

Authorised Representative name (if applicable)	Covidien Ireland Limited
Authorised Representative address and contact details	IDA Business and Technology Park Tullamore, Co. Offaly R35 H9O3 Ireland
Single Registration Number (SRN) (if available)	IE-AR-000002274

Notified body name (if applicable)	TUV SUD
Notified body number (if applicable)	0123

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

Declaration, including the attached schedule, should be printed on form as used for a Declaration of Conformity per manufacturer's QMS (e.g. manufacturer's letterhead)

Directive Certificate number(s) to which this confirmation is made (if applicable)	G1 077790 0060
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	26 May 2024
End date of extended validity/transition period	31 December 2028

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐ Expired *before* 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

  ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

  Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

  ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

Declaration, including the attached schedule, should be printed on form as used for a Declaration of Conformity per manufacturer's QMS (e.g. manufacturer's letterhead)

☒ Expired/expires *after* 20 March 2023:

Choose one applicable statement:

☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

- **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

- **Quality Management System (QMS)**

Choose one applicable statement:

☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

☐ A QMS in accordance with Article 10(9) MDR is in place.

☒ A notified body has issued the attached certificate for the MDR-compliant QMS.

- **Device(s) as listed in the attached schedule of devices**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Full Company Name	Covidien LLC
Location & Date	
Signature, Print Name, Title	Katarzyna Goode Program Manager, Regulatory Affairs
Contact Details (at least email)	rs.eudamedinquiries@medtronic.com

Declaration, including the attached schedule, should be printed on form as used for a Declaration of Conformity per manufacturer's QMS (e.g. manufacturer's letterhead)

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s) (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate**	**Notified Body name and number where the MDR application was lodged/contract signed**	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
186-0106	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
186-0106-PH	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
186-0150	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
186-0150-PH	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
186-0160	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
186-0200	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
186-0212	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	

186-0212-PH	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
186-1046	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
186-0195-AMS	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
186-0224-AMS	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
185-1016-AMS	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
186-0195-NK	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
186-0224-NK	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
186-0224-NK- RFB	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
186-0195-DM	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
186-0195-GE	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
186-0195-MR	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	

186-0224-MR	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
186-0195-SLM	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
186-0195-SF	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
186-0224-SF	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
186-0195-PH	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
186-0199-PH	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
186-0224-PH	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
186-0224- PHSPS	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
186-0195- PHSPS	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
186-0199-RFB	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
186-0201-AMS	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	

186-0107	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
186-1018-AMS	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
186-0201-NK	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
186-0201-DM	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
186-0201-GE	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
186-0201-MR	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
186-0201-SLM	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
186-0201-PH	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
186-0131	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
186-1018-PH	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
009822COV	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	

010433COV	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
015096COV	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
006912COV	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
012529COV	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
007269COV	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
012531COV	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
010177COV	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
009818COV	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
009826COV	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
012530COV	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
012532COV	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	

010340COV	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
PMC40M-GE	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
5100C	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
5100C-PA	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
5100C-PB	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
RSC-1	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
RSC-2	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
RSC-3	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
RSC-4	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
CNN	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
SNN	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	

CNN/SNN	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
SAFB-SM	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
SPFB	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
RSC-L	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
RSC-R	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
PM7100	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
PMPAMP71	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
PMAC71RSC	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
PMAC71RIC	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
PMAC71DOC	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
PMAC71RSC-L-CH1	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	

PMAC71RSC-L-CH2	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
PMAC71RSC-L-CH3	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
PMAC71RSC-L-CH4	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
PMAC71STAND	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
PMSENS71-A	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
PMSENS71-P	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
PMC71V-GE	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
VITALSYNCSW01	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
EWSSW01	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
WRSBTSW01	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
OTHJ8-10099067	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	

OTHJ8-VSENTERPINT	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
OTHJ8-APPINT	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
SCRJ8-EWSSUB	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
SCRJ8-SBTWRSUB	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
VSLICENSEBASE02	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
N85	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
N85-1	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
48127	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
MAXRI	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
MAXAI	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
MAXALI	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	

MAXII	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
MAXNI	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
MAXPI	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
MAXPACI	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
10068119	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
DS100A	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
D-YS	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
D-YSE	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
D-YSPD	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
Posey*	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
FOAM A/N	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	

FOAM P/I	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
ADH-A/N	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
ADH-P/I	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
OXI-A/N	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
OXI-P/I	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
SC-PR-I	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
SC-NEO-I	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
SC-A-I	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
901-A	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
902-I	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
903-P	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	

904-N	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
RS10	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
10005063*	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
10005941	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
10005941-SG	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
10076644	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
867193	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
10083058	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
10093313	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
DOC4	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
DOC10	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	

4-Dec	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
8-Dec	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
MC-10	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
PM10N	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
PM100N	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
PMC10GE120N	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
PMC10GE360N	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
PMC10NCH-GE	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
5015800	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
5015900	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
5030810	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	

5030840	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
5030850	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
5030860	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
5030870	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
GR101704	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
PM1000N	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
PM1000N-RR	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
PMMOD30N	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
5030880	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
5030890	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
5030900	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	

5016000	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
90041	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
90042	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
90043	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
90049	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
90044	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
90050	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
90051	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
90052	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
90053	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
90054	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	

90055	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
90056	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
502-0400A	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
502-0401A	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
502-0410A	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
502-0411A	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
502-0405A	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
502-0415A	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	
90045	G1 077790 0060	26-May-24	TÜV SÜD Product Services GmbH -- 0123	TÜV SÜD Product Services GmbH -- 0123	31-Dec-28	

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 063105 0047 Rev. 00

Manufacturer:

CA-MI S.R.L.
Via Ugo La Malfa, 13
Frazione Pilastro
43013 Langhirano (PR)
ITALY

Facility(ies):

CA-MI S.R.L.
Via Ugo La Malfa, 13, Frazione Pilastro, 43013 Langhirano (PR), ITALY

Product Category(ies):

Aerosol Therapy Equipment, Kits for Aerosol Therapy, Thermal Water Inhaler, Suction Unit, Surgical Suction Equipment, Breast Pump, Kit Accessory for Electric Breast Pump, Blood Pressure Monitor, Electronic Thermometer, Infrared Ear Thermometer, Tens Device, Pulse Oximeter

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.: ITA1319360

Valid from: 2019-10-01
Valid until: 2024-05-26

Date, 2019-10-01

ody

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
A4 / 07.17