ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

CERTIFICATO CE

Garanzia di qualità della produzione

Direttiva 93/42/CEE concernente i dispositivi medici (DDM), allegato V (dispositivi in classe IIa, IIb o III)

N° G2 17 12 31998 026

Fabbricante:

DEAS s.r.l.
Via dell'Industria 49
48014 Castelbolognese (RA)
ITALIA

Stabilimento(i):

DEAS s.r.l.
Via dell'Industria 49, 48014 Castelbolognese (RA), ITALIA

Categoria(e) di prodotto:

Dispositivi medici sterili e non sterili :

circuiti respiratori e connettori, camere di umidificazione, cateteri mount, maschere, filtri, filtri per spirometria e boccagli, palloni e unità respiratorie manuali, linee di controllo, tubi extraglottici, tracheali, tracheobronchiali, tracheostomici, introduttori, kit per tracheostomia, dispositivi per aerosol ed ossigenoterapia, valvole PEEP, dispositivi di aspirazione

Con il presente certificato, l'organismo notificato di TÜV SÜD Product Service GmbH certifica che il fabbricante sopra menzionato ha implementato un sistema di qualità per la fabbricazione ed il controllo finale dei dispositivi / categorie di dispositivi in questione secondo quanto stabilito nella direttiva DDM, allegato V. Questo sistema di qualità risponde ai requisiti della presente direttiva ed è soggetto a sorveglianze regolari. Per l'immissione sul mercato di dispositivi delle classi IIb e III, è richiesto un certificato addizionale, di cui all'allegato III.
Osservare le note riportate sul retro.

N° del rapporto: ITA1045535

Valido da: 2018-03-21
Valido fino al: 2023-03-20

Data, 2018-02-19

Stefan Preiß

TÜV SÜD PRODUCT SERVICE GMBH è Organismo Notificato con numero identificativo 0123.

Traduzione per scopi informativi. La sola versione inglese è legalmente impegnativa.

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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 17 12 31998 026

Manufacturer:

DEAS s.r.l.
Via dell'Industria 49
48014 Castel Bolognese (RA)
ITALY

Facility(ies):

DEAS s.r.l.
Via dell'Industria 49, 48014 Castel Bolognese (RA), ITALY

Product Category(ies):

Sterile and non sterile medical devices: breathing circuits and connectors, humidification chambers, catheters mount, masks, filters, spirometry filters and mouthpieces, bags and manual breathing units, monitor lines, extraglottic, tracheal, tracheal-bronchial, tracheostomy tubes, introducers, tracheostomy kits, aerosol and oxygen therapy devices, PEEP valves, suction devices

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.: ITA1045535

Valid from: 2018-03-21
Valid until: 2023-03-20

Date, 2018-02-19

Stefan Preiß

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

TÜV®

TÜV SÜD Product Service GmbH · Ridlerstraße 65 · 80339 München · Deutschland

DEAS s.r.l.,
Mr. Domenico Scardovi
via dell'Industria 49,
I-48014 Castelbolognese (RA),
Italy

Your Ref/Name	Our Ref/Name	Tel. /E-Mail	Fax	Date	Page
	ITA-1903972	+39 051 2987411		05. June 2023	1 von 7
	FAQ_2023-282	carlo.gherardi@tuvsud.com			

Notified Body Confirmation Letter

Reference: ITA-1903972

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of 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.

This letter confirms that, TÜV SÜD Product Service GmbH, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0123 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer.

DEAS s.r.l.,
via dell'Industria 49,
I-48014 Castelbolognese (RA),
Italy

SRN Number: IT-MF-000013017

Product Service

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below, see attachment:

- Table 1 identifies the devices which an MDR application has been received, written agreement concluded and for which the TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive.
- Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the TÜV SÜD Product Service GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that:

- the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or
- provided evidence that a competent authority of a Member State had granted a derogation in accordance with Article 59(1) of the MDR or
- provided evidence that a competent authority of a Member State had granted an exemption from the applicable conformity assessment procedure in accordance with Article 97(1) of the MDR respectively,

by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by EU 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

TÜV SÜD Product Service GmbH
Medical and Health Services

Signatur: Carlo Gherardi
Carlo Gherardi (5. Juni 2023 15:01 GMT+2)

E-Mail: carlo.gherardi@tuvsud.com

Carlo Gherardi
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Signatur: Hoyer Julia
Hoyer Julia (5. Juni 2023 15:20 GMT+2)

E-Mail: Julia.Hoyer@tuvsud.com

Julia Hoyer
Head of Certification Body - Deputy

Product Service

ATTACHMENT

Table 1: Devices covered by this letter and for which the TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Basic UDI-DI: **8033426 HUMIDIFIER 2H**	☐N/A or ☐ Class III ☐ Class IIb implantable non- WET device ☒ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: G1 17 12 31998 025; NB# 0123 or ☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Basic UDI-DI: **8033426 ATOMIZER 6H** **8033426 ATOMIZER-ST TW**	☐N/A or ☐ Class III ☐ Class IIb implantable non- WET device ☐ Class IIb excluding Class IIb implantable non-WET ☒ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☒ N/A or ☐ Certification as follows: Certificate #1; NB# Certificate #2; NB # or ☒ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class III implantable custom-made device		State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Basic UDI-DI: **8033426 BRONCHIALBLOCK CU** **8033426 BRONCHIALTUBES KN** **8033426 CIAGLIA KH** **8033426 CRICOTOMIA YB** **8033426 EXTRAGLOCTICS 4S** **8033426 GRIGGS TD** **8033426 NASOPHARYNGEAL 3K** **8033426 ORAL-CARE 53** **8033426 ORAL-CARE-ST UV** **8033426 TRACHEAL-TUBES 8A** **8033426AEROSOLSR** **8033426AEROSOL-STVE** **8033426AEROSOLTRACQ8** **8033426AEROSOLTRAC-STTQ** **8033426APLCONNECTORDL** **8033426APLCONNECTORSTLT** **8033426BUBBLETUBEQF** **8033426CANNULAPX** **8033426CANNULA-STNT** **8033426CHAMBERKJ** **8033426CHAMBER-STD7** **8033426CIRCUIT-STU8** **8033426CIRCUITT3** **8033426CONNECTORDS** **8033426CONNECTOR-STGL** **8033426CPAPMASK-STD7** **8033426CPAPMASKWN** **8033426ENDO-MASK-STRA** **8033426ENDO-MASKYV** **8033426FILTERSB** **8033426FILTERSPIRO-STZS** **8033426FILTERSPIROTL** **8033426FILTER-STBL** **8033426FILTERTRAC3Y** **8033426FILTERTRAC-STNH** **8033426GUIDEUK** **8033426HEATEDCIRCKX** **8033426HEATEDCIRC-STSJ** **8033426HMEFILTERAK** **8033426HMEFILTER-STA9**	☒N/A or ☐ Class III ☐ Class IIb implantable non- WET device ☐ Class IIb excluding Class IIb implantable non-WET ☒ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: G2 17 12 31998 026; NB#: 0123 or ☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
8033426INTRODUCERCE **8033426LINE-STRR** **8033426LINEZJ** **8033426MASK-STS3** **8033426MASKZC** **8033426MOUNT-STAQ** **8033426MOUNTZ3** **8033426MOUTHPIECEGD** **8033426NASALMASKCB** **8033426NASALMASK-STCJ** **8033426NEBULIZERFX** **8033426NEBULIZER-STL5** **8033426NIV-CPAPMASK7E** **8033426NIV-CPAPMASKST6J** **8033426OXYGENCONW9** **8033426OXYGENMASKLC** **8033426OXYGENMASK-STF8** **8033426OXYGENTUBEP2** **8033426OXYGENTUBE-STKW** **8033426RESERVOIRQW** **8033426RESERVOIR-ST45** **8033426STYLET57** **8033426SUCTIONCATH7J** **8033426SUCTIONCLOSE8F** **8033426SUCTIONVALVECD** **8033426SUCTIONVALVESTRT** **8033426TRACHEOCANULAH5** **8033426URMFC** **8033426URM-STX8** **8033426VALVE-ST4F** **8033426VALVEXH** **8033426WATERTRAPRT** **8033426WATERTRAP-ST3W**			
Basic UDI-DI: **8033426 BR-EXERCISERS RH** **8033426 RESP-FIXATION GJ** **8033426 AIRWAY-MANAGE 6Z** **8033426 ENDOSCOPY-MP GX** **8033426 TRACHEO-PAD HM**	☐N/A or ☐ Class III ☐ Class IIb implantable non- WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☒ Class I devices placed on the market in sterile condition	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: G2S 17 12 31998 027; NB#: 0123 or ☐ N/A - Device did not require a Notified Body certificate under Directives or

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device		☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#

Product Service

Table 2: Devices covered by this letter and for which the TÜV SÜD Product Service GmbH is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A; all devices in scope are subject to Table 1.	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☒ N/A or ☐ Certification as follows: Certificate #: Certificate #: or ☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2023-06-05	ITA1903972	Initial Letter