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Date: 2025.02.26 16:34:10 EET
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EC Certificate

mdc medical device certification GmbH
Notified Body 0483
herewith certifies that

ENDO-TECHNIK Wolfgang Griesat GmbH
Hans-Böckler-Straße 29
40764 Langenfeld
Germany

for the scope

**disinfection systems for endoscopes,
endoscopic products for single use, flushing systems
(see attachment)**

has introduced and applies a

Quality System

for the design, manufacture and final inspection.

The mdc audit has proven that this quality system
meets all requirements according to

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Annex II – excluding Section 4
of the Council Directive 93/42/EEC

of 14 June 1993 concerning medical devices.

The surveillance will be held as specified in Annex II, Section 5.

Valid from	2021-05-19
Valid until	2023-11-18
Registration no.	D1286900022
Report no.	P20-00301-206094
Stuttgart	2021-05-19

Head of Certification Body

medical device certification mdc

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-246.10.06

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0

Attachment of the certificate		
No. D1286900022	Date 2021-05-19	Page 1 of 1

Product category	Product	Class	Product code
disinfection systems for endoscopes	WASH:MASTER classic WASH:MASTER eco	IIb	11-278
endoscopic products for single use	injection needle, single use	IIa	17-569
	polypectomy snares, single use	IIb	15-989
flushing unit	AQUA:MASTER	IIa	12-300

Head of Certification Body

medical device certification mdc

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0

Supplement to the Certificate
according to 93/42/EEC, Annex II, excluding 4
page 1 of 1

Manufacturer	ENDO-TECHNIK Wolfgang Griesat GmbH
Certificate	No. D1286900022 Date: 2021-05-19 disinfection systems for endoscopes, endoscopic products for single use, flushing systems
Products concerned	disinfection systems for endoscopes, endoscopic products for single use, flushing systems
Intended Change	New company name: **Creo Medical GmbH** Hans-Böckler-Straße 29 DE-40764 Langenfeld
Review Report No.	P21-00417-224425

The intended change is in compliance with the requirements of the Directive 93/42/EEC.

This supplement is valid only in conjunction with the aforementioned Certificate.

The aforementioned Certificate is valid only in conjunction with this supplement.

This supplement is valid until: 2023-11-18
Registration no.: D1286900025
Stuttgart 2022-01-03

Head of Notified Body

medical device certification mdc

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
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Fax: +49-(0)711-253597-10

Supplement to the Certificate
according to 93/42/EEC, Annex V, 3
page 1 of 1

Manufacturer	ENDO-TECHNIK Wolfgang Griesat GmbH
Certificate	No. D1286900020 Date: 2021-04-26 disposable biopsy forceps
Products concerned	disposable biopsy forceps
Intended Change	New company name: **Creo Medical GmbH** Hans-Böckler-Straße 29 DE-40764 Langenfeld
Review Report No.	P21-00417-224423

The intended change is in compliance with the requirements of the Directive 93/42/EEC.

This supplement is valid only in conjunction with the aforementioned Certificate.

The aforementioned Certificate is valid only in conjunction with this supplement.

This supplement is valid until: 2023-11-18
Registration no.: D1286900024
Stuttgart 2022-01-03

Head of Notified Body

medical device certification mdc

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CERT 10 (DOC-18944) Ver. 0

Approved By:

Elliott Postle - Author

June 4, 2024 11:44 AM BST d3a1745f-91ca-41f2-ad0e-56289190688a

Elliott Postle - Document Control

June 4, 2024 11:45 AM BST d3a1745f-91ca-41f2-ad0e-56289190688a

Version History:

Author	Effective Date	Ver.	Status
Elliott Postle	June 4, 2024 11:45 AM BST	0	Published

CERT-10 (DOC-18944) Ver. 1

Approved By:

Elliott Postle - Author

June 24, 2024 12:53 PM BST d3a1745f-91ca-41f2-ad0e-56289190688a

Elliott Postle - Document Control

June 24, 2024 12:53 PM BST d3a1745f-91ca-41f2-ad0e-56289190688a

Version History:

Author	Effective Date	Ver.	Status
Elliott Postle	June 24, 2024 12:53 PM BST	1	Published
Elliott Postle	June 4, 2024 11:45 AM BST	0	Superseded

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Nur zur elektronischen Verbreitung

Certificate

We hereby certify the company

Creo Medical GmbH
Hans-Böckler-Straße 29
40764 Langenfeld
Germany

the introduction and application of a

Quality management system according to EN ISO 13485

in the scope

Development, manufacture, service and distribution of active endoscopic irrigation/flushing devices, and active endoscopic cleaning and disinfection devices
Distribution of associated accessories

An audit by mdc has proven that this quality management system meets the requirements of the following standard:

EN ISO 13485:2016 + AC:2018 + A11:2021 - ISO 13485:2016
Medical devices – Quality management systems – Requirements for regulatory purposes

Valid from	2024-11-04	Registration No.	D1286900028
Valid until	2027-11-03	Report No.	P24-01198-310309

Stuttgart, 2024-11-04

Certification Body

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DAkkS Deutsche Akkreditierungsstelle D-ZM-16002-06-00

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Date: 2025.02.13 16:22:11 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Creo Medical GmbH
Hans-Böckler-Str. 29
Langenfeld
40764
Germany
19 Jun 2024

Notified Body Confirmation Letter

Reference: EU2023-607/893597

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, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** 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:

Creo Medical GmbH
Hans-Böckler-Str. 29
Langenfeld
40764
Germany
SRN Number: DE-MF-000005261

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB 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 NB 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 or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or 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 BSI Group The Netherlands B.V.,

Graeme Tunbridge
Senior Vice President, Medical Devices

Table 1: Devices covered by this letter and for which the NB 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
Aqua:Master 42503598AQUA:MASTERN5	Class IIa	N/A	Certificate no. D1286900022, NB 0483
Wash:Master Eco 42503598WASH:MASTECOYB	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate no. D1286900022, NB 0483

Table 2: Devices covered by this letter and for which the NB 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	N/A	N/A	N/A

Confirmation Letter Revision History

Date	Action
2024/06/19	Initial issue