Blazejewski MEDI-TECH GmbH
Rheinstr. 1
79350 Sexau
Deutschland

Notified Body Confirmation Letter

Reference: D1038900028

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, mdc medical device certification GmbH (Kriegerstr. 6, 70191 Stuttgart, Germany), a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0483 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:

Blazejewski MEDI-TECH GmbH
Rheinstr. 1
79350 Sexau
Deutschland
SRN: DE-MF-000005467

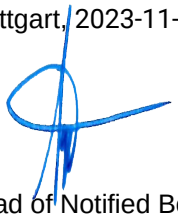
The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the 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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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 Regulation (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)

Stuttgart, 2023-11-22



Head of Notified Body

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
Arthroscope (rigid without working channel)	Class IIa	N/A	Certificate D1038900025
Hysteroscope (rigid without working channel)	Class IIa	N/A	Certificate D1038900025
Laparoscope (rigid without working channel)	Class IIa	N/A	Certificate D1038900025
Cystoscope (rigid without working channel)	Class IIa	N/A	Certificate D1038900025
Laparoscope (rigid with working channel)	Class IIa	N/A	Certificate D1038900025
Nephroscope (rigid with working channel)	Class IIa	N/A	Certificate D1038900025
Cystoscope (rigid with working channel)	Class IIa	N/A	Certificate D1038900025
Endoscopes for Discectomy (rigid with working channel)	Class IIa	N/A	Certificate D1038900025
Ureterorenoscopes (rigid with working channel)	Class IIa	N/A	Certificate D1038900025

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	NB internal reference traceable to each version of the letter	Action
2023-11-22	D1038900028	Initial

mdc medical device certification GmbH
Kriegerstraße 6 | 70191 Stuttgart | Germany | www.mdc-ce.de

EC Certificate

mdc medical device certification GmbH
Notified Body 0483
herewith certifies that

Blazejewski MEDI-TECH GmbH
Rheinstraße 1
79350 Sexau
Germany

for the scope

rigid endoscopes with and without working channel
(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

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	2018-11-22
Valid until	2023-11-21
Registration no.	D1038900025
Report no.	P18-00703-121205
Stuttgart	2018-11-15

Head of Certification Body

medical device certification mdc

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

mdc medical device certification GmbH
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Attachment of the certificate

No. D1038900025 Date 2018-11-15 Page 1 of 1

Product category	Product	Class	Product code
rigid endoscopes without working channel	Arthroscope	IIa	10-198
	Hysteroscope	IIa	12-081
	Laparoscope	IIa	12-291
	Thoracoscope	IIa	14-047
	Cystoscope	IIa	17-145
rigid endoscopes with working channel	Laparoscope	IIa	12-291
	Nephroscope	IIa	15-290
	Cystoscope	IIa	17-145
	Diskectomy system	IIa	17-575
	Ureterorenoscope	IIa	17-690

Head of Certification Body

medical device certification mdc

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