DQS Medizinprodukte GmbH | August-Schanz-Str. 21 | 60433 Frankfurt am Main

FMZ GmbH

Charles-Darwin-Ring 3a, 18059 Rostock

Germany

2023-08-30

Notified Body Confirmation Letter

Reference: 204456

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 device

This letter confirms that, DQS Medizinprodukte GmbH, a Notified Body designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0297 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:

Company:	**FMZ GmbH**
Street:	Charles-Darwin-Ring 3a
City:	18059 Rostock
Country:	Germany

SRN (if available, otherwise: N/A): DE-MF-000006688

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry, or provided evidence that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

A. Königshoven

Alina Königshoven

Regulatory Affairs Manager

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 and Basic UDI-DI (as proposed by the manufacturer within the application)	Basis-UDI-DI	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
Tube-Line BONITex®	++E8660598	III	Tube-Line BONITex®	Certificate-no. 204456 MR2, ID (NB) 0297
Slim-Line BONITex®	Kugel: ++E8660292 Konus: ++E866018Y	III	Slim-Line BONITex®	Certificate-no. 204456 MR2, ID (NB) 0297
Tube-Line DUOTex®	++E8660394	IIb	Tube-Line DUOTex®	Certificate-no. 204456 MR2, ID (NB) 0297
Slim-Line DUOTex®	Kugel: ++E8660292 Konus: ++E866018Y	IIb	Slim-Line DUOTex®	Certificate-no. 204456 MR2, ID (NB) 0297
Universalbohrer	++E8663097	IIa	Universalbohrer	Certificate-no. 204456 MR2, ID (NB) 0297
Finisher	++E8663199	IIa	Finisher	Certificate-no. 204456 MR2, ID (NB) 0297
Rosenbohrer	++E866329B	IIa	Rosenbohrer	Certificate-no. 204456 MR2, ID (NB) 0297
Corticalis-Bohrer	++E866339D	IIa	Corticalis-Bohrer	Certificate-no. 204456 MR2, ID (NB) 0297
2,0mm-Bohrer	++E866349F	IIa	2,0mm-Bohrer	Certificate-no. 204456 MR2, ID (NB) 0297
2,8mm-Bohrer	++E866359H	IIa	2,8mm-Bohrer	Certificate-no. 204456 MR2, ID (NB) 0297

Trepan Bohrer	++E866369K	IIa	Trepan Bohrer	Certificate-no. 204456 MR2, ID (NB) 0297
Vorbohrer	++E866379M	IIa	Vorbohrer	Certificate-no. 204456 MR2, ID (NB) 0297
2,0mm Bohrer Slim-Line	++E866389P	IIa	2,0mm Bohrer Slim-Line	Certificate-no. 204456 MR2, ID (NB) 0297
3-Kant Bohrer Slim-Line	++E866399R	IIa	3-Kant Bohrer Slim-Line	Certificate-no. 204456 MR2, ID (NB) 0297
Provisorische Pfosten	++E8661397	IIb	Provisorische Pfosten	Certificate-no. 204456 MR2, ID (NB) 0297
Pfosten Titan gerade	++E8661499	IIb	Pfosten Titan gerade	Certificate-no. 204456 MR2, ID (NB) 0297
Pfosten Titan gewinkelt 10°	++E8661499	IIb	Pfosten Titan gewinkelt 10°	Certificate-no. 204456 MR2, ID (NB) 0297
Pfosten Titan gewinkelt 20°	++E8661499	IIb	Pfosten Titan gewinkelt 20°	Certificate-no. 204456 MR2, ID (NB) 0297
Teleskoppfosten	++E866199K	IIb	Teleskoppfosten	Certificate-no. 204456 MR2, ID (NB) 0297
Kugelpfosten	++E8662298	IIb	Kugelpfosten	Certificate-no. 204456 MR2, ID (NB) 0297
Ästhetikpfosten	++E866159B	IIb	Ästhetikpfosten	Certificate-no. 204456 MR2, ID (NB) 0297
Stegpfosten	++E866249C	IIb	Stegpfosten	Certificate-no. 204456 MR2, ID (NB) 0297
Titanbasis	++E866169D	IIb	Titanbasis	Certificate-no. 204456 MR2, ID (NB) 0297
Gingivaformer	++E8661295	IIb	Gingivaformer	Certificate-no. 204456 MR2, ID (NB) 0297

Angussfähiger Aufbau	++E866189H	IIb	Angussfähiger Aufbau	Certificate-no. 204456 MR2, ID (NB) 0297
Klebebasis	++E866259E	IIb	Klebebasis	Certificate-no. 204456 MR2, ID (NB) 0297
Angulationskonzept (Systembestandteile 0° Pfosten ZrN beschichtet)	++E866269G	IIb	Angulationskonzept (Systembestandteile 0° Pfosten ZrN beschichtet)	Certificate-no. 204456 MR2, ID (NB) 0297
Kappen (Slim-Line)	++E866259E	IIb	Kappen (Slim-Line)	Certificate-no. 204456 MR2, ID (NB) 0297
Multipfosten	++E866179F	IIb	Multipfosten	Certificate-no. 204456 MR2, ID (NB) 0297
Locator® Aufbau	++E8662094	IIb	Locator® Aufbau	Certificate-no. 204456 MR2, ID (NB) 0297
P-Switch	++E866299N	IIb	P-Switch	Certificate-no. 204456 MR2, ID (NB) 0297
Abdeckschraube	++E8661193	IIb	Abdeckschraube	Certificate-no. 204456 MR2, ID (NB) 0297
Abdeckschraube spezial	++E8661193	IIb	Abdeckschraube spezial	Certificate-no. 204456 MR2, ID (NB) 0297
Stegschraube	++E866279J	IIb	Stegschraube	Certificate-no. 204456 MR2, ID (NB) 0297
Zentralschraube	++E866279J	IIb	Zentralschraube	Certificate-no. 204456 MR2, ID (NB) 0297
alpha-loc	++E8662094	IIb	alpha-loc	Certificate-no. 204456 MR2, ID (NB) 0297
easyfixbase® Abutments (Angulationskonzept)	++E866269G	IIb	easyfixbase® Abutments (Angulationskonzept)	Certificate-no. 204456 MR2, ID (NB) 0297

BONITmatrix®	++E866409A	III	BONITmatrix®	Certificate-no. 204456 MR2, ID (NB) 0297
Fixierelement für Dental-Schablonen	++E866289L	IIa	Fixierelement für Dental-Schablonen	Certificate-no. 204456 MR2, ID (NB) 0297

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 and Basic UDI-DI (as proposed by the manufacturer within the 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**
Device 4 or N/A (to be specified in case there are no devices to be listed in Table 2)	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 (to be specified in case there are no devices to be listed in Table 2)	N/A Identification of the corresponding device under MDD/AIMDD N/A (to be specified in case there are no devices to be listed in Table 2)	Certificate #1 (NB #1) Certificate #2 (NB #2) N/A - Device did not require a Notified Body certificate under Directives N/A (to be specified in case there are no devices to be listed in Table 2)
Device 5 or N/A (to be specified in	Class III	N/A	Certificate #1 (NB #1) Certificate #2 (NB #2)

Device name and Basic UDI-DI (as proposed by the manufacturer within the 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
case there are no devices to be listed in Table 2)	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 (to be specified in case there are no devices to be listed in Table 2)	Identification of the corresponding device under MDD/AIMDD N/A (to be specified in case there are no devices to be listed in Table 2)	N/A - Device did not require a Notified Body certificate under Directives N/A (to be specified in case there are no devices to be listed in Table 2)
Device 6 or N/A (to be specified in case there are no devices to be listed in Table 2)	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	N/A Identification of the corresponding device under MDD/AIMDD N/A (to be specified in case there are no devices to be listed in Table 2)	Certificate #1 (NB #1) Certificate #2 (NB #2) N/A - Device did not require a Notified Body certificate under Directives N/A (to be specified in case there are no devices to be listed in Table 2)

Device name and Basic UDI-DI (as proposed by the manufacturer within the 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 that qualify as re-usable surgical instruments Class III implantable custom-made device N/A (to be specified in case there are no devices to be listed in Table 2)		

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023-08-30	170771983	Initial issue