

HumanTech Dental GmbH
Gewerbestraße 5
71144 Steinenbronn

2024-05-06

Notified Body Confirmation Letter

Reference: 170769628

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, 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:

HumanTech Dental GmbH

Gewerbestraße 5

71144 Steinenbronn

Germany

SRN: DE-MF-000010596

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry, or provided evidence that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,



Tim Unverzagt

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)	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
<p>RATIOPLANT® Implants and Prosthetics</p> <p>Basic-UDI-DI:</p> <p>42516713001L7 42516713002L9 42516713003LB 42516713004LD 42516713005LF 42516713006LH 42516713007LK 42516713008LM 42516713009LP 42516713010L8</p>	<p>Class IIb</p>	<p>Dental Implants; IIb Cover Screws; IIa Abutments; IIb</p>	<p>Certificate unique ID: 170769628</p> <p>Certificate registration no.: 540288 MR2</p> <p>NB Identification: DQS MED 0297</p>
<p>HumanTech Dental Instrumentation IIa</p> <p>Basic-UDI-DI:</p> <p>42516713011LA 42516713012LC 42516713013LE 42516713014LG 42516713015LJ 42516713016LL 42516713017LN 42516713019LS 42516713022LF 42516713029LV 42516713042LM</p>	<p>Class IIa</p>	<p>Dental Instruments IIa</p>	<p>Certificate unique ID: 170769628</p> <p>Certificate registration no.: 540288 MR2</p> <p>NB Identification: DQS MED 0297</p>

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
HumanTech Dental Instrumentation Ir Basic-UDI-DI: 42516713018LQ 42516713020LB 42516713021LD 42516713023LH 42516713024LK 42516713025LM 42516713026LP 42516713027LR 42516713028LT 42516713030LE 42516713031LG 42516713032LJ 42516713033LL 42516713034LN 42516713035LQ 42516713036LS 42516713037LU 42516713038LW 42516713039LY 42516713040LH 42516713041LK 42516713043LP 42516713044LR	Class Ir + Accessories	Dental Instruments; I Dental Accessories	self-declared under MDD

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
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024-05-06	170769628	Initial issue