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

S&S Scheftner GmbH

Dekan-Laist-Str. 52
55129 Mainz
Germany

2024-09-26

Notified Body Confirmation Letter

Reference: 1000199860

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:

S&S Scheftner GmbH

Dekan-Laist-Str. 52
55129 Mainz
Germany
SRN: DE-MF-000006535

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry, or provided evidence that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

Andreas Dreimann
Senior 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
N/A (no devices to be listed in Table 1)	N/A (no devices to be listed in Table 1)	N/A (no devices to be listed in Table 1)	N/A (no devices to be listed in Table 1)

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 names for NPM partial denture alloys with Basic UDI-DI 426020785NPMpartialdentZU: Modelstar S Modelstar S 250 g Modelstar S 50 g (Muster) MoguCast EH MoguCast EH, 50 g (Muster) Starbond Co Starbond Co 250 g Starbond Co 25 g (Muster) NovoChrom FH 100 g NovoChrom FH 1 kg Cleon MG 1 kg	Class IIa	N/A	7279DE410181213 7279GB410181213 (Certification ANNEX II of Medical Device Directive 93/42/EEC) by Medcert GmbH (Identification number: 0482)
Device names for NPM veneering alloys with Basic UDI-DI 426020785NPM-veneeringCL: MoguCera C MoguCera C 25 g (Muster) Starbond Easy Starbond Easy 250 g Starbond Easy 25 g (Muster) Cleon KB 1 kg Starbond CoS Starbond CoS 250 g Starbond CoS 25 g (Muster) NovoChrom C 1 kg NovoChrom C 100 g ecoNEM Star 1000 g ecoNEM Star 250 g	Class IIa	N/A	7279DE410181213 7279GB410181213 (Certification ANNEX II of Medical Device Directive 93/42/EEC) by Medcert GmbH (Identification number: 0482)

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 names for Ni veneering alloys with Basic UDI-DI 426020785Ni-veneeringNR: MoguCera N MoguCera N 25 g (Muster) NovoChrom N 100 g NovoChrom N 1 kg Starbond Ni Starbond Ni 25 g (Muster)	Class IIa	N/A	7279DE410181213 7279GB410181213 (Certification ANNEX II of Medical Device Directive 93/42/EEC) by Medcert GmbH (Identification number: 0482)
Device names for Titanium dental materials with Basic UDI-DI 426020785TitaniumJT: Starbond Ti4 Disc 8 mm Starbond Ti4 Disc 10 mm Starbond Ti4 Disc 12 mm Starbond Ti4 Disc 14 mm Starbond Ti4 Disc 15 mm Starbond Ti4 Disc 16 mm Starbond Ti4 Disc 18 mm Starbond Ti4 Disc 25 mm Starbond Ti4 Disc 30 mm Starbond Ti4 Disc 8 mm Starbond Ti4 Disc 10 mm Starbond Ti4 Disc 12 mm Starbond Ti4 Disc 13,5 mm Starbond Ti4 Disc 15 mm Starbond Ti4 Disc 16 mm Starbond Ti4 Disc 18 mm Starbond Ti4 Disc 25 mm Starbond Ti4 Disc 30 mm Novobond Ti4 Disc (several UDI-Dis) CORiTEC Titan Grade 5 Disc 10 mm CORiTEC Titan Grade 5 Disc 12 mm CORiTEC Titan Grade 5 Disc 15 mm CORiTEC Titan Grade 5 Disc 18 mm Starbond Ti5 Disc 8 mm Starbond Ti5 Disc 10 mm	Class IIa	N/A	7279DE410181213 7279GB410181213 (Certification ANNEX II of Medical Device Directive 93/42/EEC) by Medcert GmbH (Identification number: 0482)

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
Starbond Ti5 Disc 12 mm Starbond Ti5 Disc 14 mm Starbond Ti5 Disc 15 mm Starbond Ti5 Disc 16 mm Starbond Ti5 Disc 18 mm Starbond Ti5 Disc 20 mm Starbond Ti5 Disc 25 mm Starbond Ti5 Disc 30 mm Starbond Ti5 Disc 8 mm Starbond Ti5 Disc 10 mm Starbond Ti5 Disc 12 mm Starbond Ti5 Disc 13,5 mm Starbond Ti5 Disc 15 mm Starbond Ti5 Disc 16 mm Starbond Ti5 Disc 18 mm Starbond Ti5 Disc 25 mm Starbond Ti5 Disc 30 mm Starbond Ti5 Block 13 mm Starbond Ti5 Block 15 mm Starbond Ti5 Block 16 mm Starbond Ti5 Block 18 mm Titan BioStar °5, Ø 98,3 mm, H 08 mm Titan BioStar °5, Ø 98,3 mm, H 10 mm Titan BioStar °5, Ø 98,3 mm, H 12 mm Titan BioStar °5, Ø 98,3 mm, H 13.5 mm Titan BioStar °5, Ø 98,3 mm, H 15 mm Titan BioStar °5, Ø 98,3 mm, H 18 mm Titan BioStar °5, Ø 98,3 mm, H 20 mm Novobond Ti5 Disc (several UDI-DIs) Starbond Ti4 Powder 45 2,5 kg Starbond Ti4 Powder 45 5 kg Starbond Ti5 Powder 45 2,5 kg Starbond Ti5 Powder 45 5 kg TiplaDur23 2,5 kg TiplaDur23 5 kg			
Device names for CoCrWMo milling discs with Basic UDI-DI 426020785CoCrWMo-millVL: Starbond CoS Disc basic 14 mm Starbond CoS Disc basic 18 mm Starbond CoS Disc basic 12 mm Starbond CoS Disc basic 8 mm	Class IIa	N/A	7279DE410181213 7279GB410181213 (Certification ANNEX II of Medical Device Directive 93/42/EEC)

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
Starbond CoS Disc basic 10 mm Starbond CoS Disc basic 15 mm Starbond CoS Disc basic 16 mm Starbond CoS Disc basic 25 mm Starbond CoS Disc basic 30 mm Starbond CoS Disc basic 13,5 mm Starbond CoS Disc basic 18 mm Starbond CoS Disc basic 12 mm Starbond CoS Disc basic 8 mm Starbond CoS Disc basic 10 mm Starbond CoS Disc basic 15 mm Starbond CoS Disc basic 16 mm Starbond CoS Disc basic 25 mm Starbond CoS Disc basic 30 mm			by Medcert GmbH (Identification number: 0482)
Device names for CoCrMo milling disc with Basic UDI-DI 426020785CoCrMo-millKD: MoguCera C Disc 8 mm MoguCera C Disc 10 mm MoguCera C Disc 12mm MoguCera C Disc 14 mm MoguCera C Disc 15 mm MoguCera C Disc 16 mm MoguCera C Disc 18 mm MoguCera C Disc 20 mm MoguCera C Disc 25 mm MoguCera C Disc 30 mm MoguCera C Disc 8 mm MoguCera C Disc 10 mm MoguCera C Disc 12mm MoguCera C Disc 13,5 mm MoguCera C Disc 15 mm MoguCera C Disc 16 mm MoguCera C Disc 18 mm MoguCera C Disc 20 mm MoguCera C Disc 25 mm MoguCera C Disc 30 mm NovoCera C Disc (several UDI-DIs) Fusionis Disc 18 mm Fusionis Disc 25 mm Fusionis Disc 18 mm Fusionis Disc 25 mm	Class IIa	N/A	7279DE410181213 7279GB410181213 (Certification ANNEX II of Medical Device Directive 93/42/EEC) by Medcert GmbH (Identification number: 0482)

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
CORiTEC CoCr Mo Disc 10 mm CORiTEC CoCr Mo Disc 12 mm CORiTEC CoCr Mo Disc 15 mm CORiTEC CoCr Mo Disc 18 mm			
Device names for CoCrW milling disc with Basic UDI-DI 426020785CoCrW-mill9X: Starbond Easy Disc 8 mm Starbond Easy Disc 10 mm Starbond Easy Disc 12 mm Starbond Easy Disc 14 mm Starbond Easy Disc 15 mm Starbond Easy Disc 16 mm Starbond Easy Disc 18 mm Starbond Easy Disc 20 mm Starbond Easy Disc 25 mm Starbond Easy Disc 30 mm Starbond Easy Disc 8 mm Starbond Easy Disc 10 mm Starbond Easy Disc 12 mm Starbond Easy Disc 13,5 mm Starbond Easy Disc 15 mm Starbond Easy Disc 16 mm Starbond Easy Disc 18 mm Starbond Easy Disc 20 mm Starbond Easy Disc 25 mm Starbond Easy Disc 30 mm Novobond Easy Disc (several UDI-DIs)	Class IIa	N/A	7279DE410181213 7279GB410181213 (Certification ANNEX II of Medical Device Directive 93/42/EEC) by Medcert GmbH (Identification number: 0482)
Device names for CoCrWMo powders with Basic UDI-DI 426020785CoCrWMo-powderRM: Starbond CoS Powder 45 5 kg Starbond CoS Powder 16 10 kg Starbond CoS Powder 16 5 kg Starbond CoS Powder 30 10 kg Starbond CoS Powder 30 5 kg	Class IIa	N/A	7279DE410181213 7279GB410181213 (Certification ANNEX II of Medical Device Directive 93/42/EEC) by

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
Starbond CoS Powder 30+ 10 kg Starbond CoS Powder 30+ 5 kg Starbond CoS Powder 45 10 kg Starbond CoS Powder 55 5 kg Starbond CoS Powder 55 10 kg Fusion AM Powder 45 5 kg Fusion AM Powder 45 10 kg Starbond Easy Powder 30 5 kg Starbond Easy Powder 30 10 kg Starbond Easy Powder 30+ 5 kg Starbond Easy Powder 30+ 10 kg Starbond Easy Powder 55 5 kg Starbond Easy Powder 55 10 kg i-ProMelt			Medcert GmbH (Identification number: 0482)
Device names for CoCrMo powder with Basic UDI-DI 426020785CoCrMo-powderYR: Modelstar S Powder 16 5 kg Modelstar S Powder 16 10 kg Modelstar S Powder 65 5 kg Modelstar S Powder 65 10 kg	Class IIa	N/A	7279DE410181213 7279GB410181213 (Certification ANNEX II of Medical Device Directive 93/42/EEC) by Medcert GmbH (Identification number: 0482)
Device names for DentalResins with Basic UDI-DI 426020785DentalResinSN: Plastopress LT (several UDI-DIs) Plastopress Jet (several UDI-DIs) PlastoDon N (several UDI-DIs) PlastoDur (several UDI-DIs)	Class IIa	N/A	7279DE414210525A 7279GB414210525A (Certification ANNEX V of Medical Device Directive 93/42/EEC) by Medcert GmbH (Identification number: 0482)

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
20th of June 2023	not given	Initial issue
13th of July 13 2023	not given	Certificate number adapted to reflect English version of certificate by Medcert GmbH
16th of November 2023	not given	Certificate 7279GB414210525A is according to MDD ANNEX V (not ANNEX II), administrative correction