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

Ortho Solutions GmbH

Eltastraße 2

78573 Wurmlingen

Germany

2024-06-04

Notified Body Confirmation Letter

Reference: 170773901

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:

Ortho Solutions GmbH

Eltastraße 2

78573 Wurmlingen

Germany

SRN: DE-MF-000005535

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry, or provided evidence that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

i.A. Stefan Theuss

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
Bone fixation plates 4049468600000001AY	Class IIb implantable non-WET device	N/A	Certificate registration number: 548484 MR2 Certificate ID: 170773901 Notified Body: 0297 DQS Medizinprodukte GmbH
Bone fixation screws 4049468600000002B2	Class IIb implantable non-WET device	N/A	Certificate registration number: 548484 MR2 Certificate ID: 170773901 Notified Body: 0297 DQS Medizinprodukte GmbH
Drill 4049468600000003B4	Class IIa	N/A	Certificate registration number: 548484 MR2 Certificate ID: 170773901 Notified Body: 0297 DQS Medizinprodukte GmbH
Thread milling cutter 4049468600000004B6	Class IIa	N/A	Certificate registration number: 548484 MR2 Certificate ID: 170773901 Notified Body:

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
			0297 DQS Medizinprodukte GmbH
Tap 4049468600000005B8	Class IIa	N/A	Certificate registration number: 548484 MR2 Certificate ID: 170773901 Notified Body: 0297 DQS Medizinprodukte GmbH
Guide wire 4049468600000006BA	Class IIa	N/A	Certificate registration number: 548484 MR2 Certificate ID: 170773901 Notified Body: 0297 DQS Medizinprodukte GmbH

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
Bending device 4049468600000007BC	Class I devices that qualify as re-usable surgical instruments	N/A	N/A – Device did not require a Notified Body certificate under Directives
Drilling aid 4049468600000008BE	Class I devices that qualify as re-usable surgical instruments	N/A	N/A – Device did not require a Notified Body certificate under Directives
Wire cutting pliers 4049468600000009BG	Class I devices that qualify as re-usable surgical instruments	N/A	N/A – Device did not require a Notified Body certificate under Directives
Elevatorium 4049468600000010AZ	Class I devices that qualify as re-usable surgical instruments	N/A	N/A – Device did not require a Notified Body certificate under Directives
Centering sleeve / guide shaft 4049468600000011B3	Class I devices that qualify as re-usable surgical instruments	N/A	N/A – Device did not require a Notified Body certificate under Directives
Handle / Handpiece / Instruments for implantation of trauma implants 4049468600000012B5	Class I devices that qualify as re-usable surgical instruments	N/A	N/A – Device did not require a Notified Body certificate under Directives
Bone / plate holding forceps 4049468600000013B7	Class I devices that qualify as re-usable surgical instruments	N/A	N/A – Device did not require a Notified Body certificate under Directives
Gauge 4049468600000014B9	Class I devices that qualify as re-usable	N/A	N/A – Device did not require a Notified

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
	surgical instruments		Body certificate under Directives
Positioning gauge 4049468600000015BB	Class I devices that qualify as re-usable surgical instruments	N/A	N/A – Device did not require a Notified Body certificate under Directives
Retractor 4049468600000016BD	Class I devices that qualify as re-usable surgical instruments	N/A	N/A – Device did not require a Notified Body certificate under Directives
Screwdriver 4049468600000017BF	Class I devices that qualify as re-usable surgical instruments	N/A	N/A – Device did not require a Notified Body certificate under Directives
Connecting screw 4049468600000018BH	Class I devices that qualify as re-usable surgical instruments	N/A	N/A – Device did not require a Notified Body certificate under Directives
Target device 4049468600000019BK	Class I devices that qualify as re-usable surgical instruments	N/A	N/A – Device did not require a Notified Body certificate under Directives
Instruments for implantation of trauma implants 4049468600000020B4 4049468600000022B8 4049468600000023BA 4049468600000024BC 4049468600000025BE 4049468600000026BG 4049468600000027BJ 4049468600000028BL	Class I devices that qualify as re-usable surgical instruments	N/A	N/A – Device did not require a Notified Body certificate under Directives

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024-06-04	170773901	Initial issue
	Cert-ID	description of change (e.g. addition of device XYZ to Table 1)
	Cert-ID	description of change (e.g. removal of device XYZ from Table 2)