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

Black & Black Surgical, Inc.

5175 S Royal Atlanta Dr.

Tucker, GA 30084, USA

05-06-2024

Notified Body Confirmation Letter

Reference: 170772346

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:

Black & Black Surgical, Inc.

5175 S Royal Atlanta Dr.

Tucker, GA 30084, USA

SRN: US-MF-000033124

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry, or provided evidence that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)	**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**
Suction and irrigation Cannulas 08403298CLS2019P	Class lla	Suction and irrigation cannulas	Certificate ID: 170726208 Certificate registration no. 515494 MR5
Suction and irrigation tubing for liposuction 08403298CLS2029R	Class lla	Suction and irrigation tubes	Certificate ID: 170726208
Peristaltic pump 08403298CLS2049V	Class lla	Vitruvian Infiltration Pump	Certificate registration no. 515494 MR5
Aspirator 08403298CLS2039T	Class lla	Aspirator	Certificate registration no. 515494 MR5

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
Cutting Devices **08403298001604JL** **08403298001603JJ** **08403298001611JH** **08403298013601K7** **08403298001607JS** **08403298001610JF** **08403298001601JE** 08403298001616JT	Class I (reusable)	Reusable surgical instruments	N/A
Ablating Devices **08403298002602JP** **08403298023601KJ** 08403298002601JM	Class I (reusable)	Reusable surgical instruments	N/A

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
Holding Devices **08403298003601JU** **08403298003602JW** **08403298003610JV** **08403298003606K6** **08403298003615K7** **08403298003614K5** **08403298013601K7** **08403298003612JZ** **08403298003611JX** **08403298003608KA** **08403298003613K3** **08403298023601KJ** **08403298003604K2** 08403298003605K4	Class I (reusable)	Reusable surgical instruments	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024-06-05	ID 170772346	Initial issue