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

OASIS® Medical, Inc.

510 – 528 S. Vermont Avenue

Glendora, CA, 91741

United States of America

2023-06-23

Notified Body Confirmation Letter

Reference: 288050 MR2

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:

OASIS® Medical, Inc.

510 – 528 S. Vermont Avenue

Glendora, CA, 91741

United States of America

SRN: N/A

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry, or provided evidence that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

Natalie Wimmer

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
Lacrimal Plugs - **SOFT PLUG® Silicone Punctum Plug (REF 6610~6614, with -S, -D, -FC, -SFC; REF 7710~7714, with -S, -D, 7712-FC~7714-FC)** **08458190SPXXXX36237RP**	Class IIb implantable non-WET device	SOFT PLUG® Silicone Punctum Plugs	288050 MR2 (NB 0297)
Lacrimal Plugs - **SOFT PLUG® Extended Duration Plug (640*)** **08458190ED64XX36237LK**	Class IIb implantable non-WET device	SOFT PLUG® Extended Duration Plugs	288050 MR2 (NB 0297)
Lacrimal Plugs - **SOFT PLUG® Extended Duration 180 Canalicular Plug (620*)** **08458190ED62XX36237KD**	Class IIb implantable non-WET device	SOFT PLUG® Extended Duration 180 Canalicular Plugs	288050 MR2 (NB 0297)
Lacrimal Plugs - **FORM FIT® Hydrogel Canalicular Plug (6303, 6303-T, B-6303)** **08458190FF630336237KB**	Class IIb implantable non-WET device	FORM FIT® Hydrogel Canalicular Plugs	288050 MR2 (NB 0297)

Disposable Microsurgical Instruments - **Disposable Ophthalmic Cannula (40**)** **08458190DI40XX47610LV, 08458190DI40XX46705M2, 08458190DI40XX10575K2, 08458190DI40XX47365M7, 08458190DI40XX12319JU, 08458190DI40XX47007LA**	Class IIa	Disposable Microsurgical Instruments	288050 MR2 (NB 0297)
Microsurgical Knives - **PremierEdge® Microsurgical Knives (PE*)** **08458190PEXXXX46741DN**	Class IIa	PremierEdge® Microsurgical Knives	288050 MR2 (NB 0297)
HPMC Viscoelastics - **VISCO SHIELD® HPMC Viscoelastic (8,000 and 20,000 cps) (Injectable: 51082, 5122)** **08458190VSHPMC35907Z7**	Class IIb excluding Class IIb implantable non-WET	VISCO SHIELD® HPMC Viscoelastic (8,000 cps and 20,000 cps)	288050 MR2 (NB 0297)
N/A **(no MDR application)**	N/A	VISCO SHIELD® HPMC Viscoelastic Topical (8,000 cps)	288050 MR2 (NB 0297)
PVA Foam Products - **SOFT CELL® PVA Foam Surgical Spears (0525)** **08458190PVA5XX13704ND**	Class I devices placed on the market in sterile condition	SOFT CELL® PVA Foam Surgical Spears	288050 MR2 (NB 0297)
N/A **(no MDR application)**	N/A	Surgical Marking Pen	288050 MR2 (NB 0297)
Iris Expander - **OASIS® Iris Expander (9700, 9700-S, 9625, 9625-S)** **08458190IE9XXX46698HY**	Class IIa	OASIS® Iris Expander	288050 MR2 (NB 0297)
N/A **(no MDR application)**	N/A	Lacrimal Instruments	288050 MR2 (NB 0297)

Collagen Corneal Shield- **SOFT SHIELD® Collagen Shield (7002, 7012, 7024, 7072)** **08458190CS70XX17652WL**	Class III	SOFT SHIELD® Collagen Shields	288050 MR2 (NB 0297) 288050 MRA-TSE (NB 0297)
N/A **(no MDR application)**	N/A	Iris Retractor	288050 MR2 (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
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023-06-20	01_288050 MR2	Initial issue
2023-06-23	02_288050 MR2	Addition of MRA-TSE Certificate reference