

Laboratoires Anios

1 rue de l'Espoir
59260 Lezennes
France

Date: 2024-04-09

Notified Body Confirmation Letter Reference: 1000172972

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:

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SRN: FR-MF-000011756

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry, or provided evidence that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 handwritten signature in blue ink, appearing to read 'L. Breslau'.

Lena Breslau
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
ANIOS CLEAN EXCEL D-, ANIOXY SPRAY WS, ANIOSYME PRIME, ANIOSYME X3, ANIOSYME XL3, Instrunet Inibsa Ins Universal, MICRO 10+, SALVANIOS pH10, SALVANIOS PREMIUM Basic UDI-DI 359761LA2A482CLIY3	Class IIa	N/A	Certificate number 31390 rev. 21 NB 0459
ANIOS QUICK WIPES, INSTRUNET INIBSA TOALLITAS, UNISEPTA PLUS WIPES Basic UDI-DI 359761LA2A462DWIYK	Class IIa	N/A	Certificate number 31390 rev. 21 NB 0459
ANIOSPRAY QUICK, ANIOSPRAY SURF 29, INSTRUNET INIBSA SPRAY Basic UDI-DI 359761LA2A462DLIXJ	Class IIa	N/A	Certificate number 31390 rev. 21 NB 0459
INCIDIN OXYFOAM NG Basic UDI-DI 359761LA2A452TLIZP	Class IIa	N/A	Certificate number 31390 rev. 21 NB 0459
INCIDIN OXYWIPE NG Basic UDI-DI	Class IIa	N/A	Certificate number 31390 rev. 21

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
359761LA2A452NWIZS			NB 0459
INCIDIN PREMIUM FOAM Basic UDI-DI 359761LA2A482TLI2T	Class IIa	N/A	Certificate number 31390 rev. 21 NB 0459
SURFA SAFE PREMIUM, SURFANIOS PREMIUM, SURFANIOS PREMIUM MD Basic UDI-DI 359761LA2A482NLIZS	Class IIa	N/A	Certificate number 31390 rev. 21 NB 0459
WIP ANIOS EXCEL Basic UDI-DI 359761LA2A482TWI3U	Class IIa	N/A	Certificate number 31390 rev. 21 NB 0459
X CIDOL 2 Basic UDI-DI 359761LA2A472NLIZF	Class IIa	N/A	Certificate number 31390 rev. 21 NB 0459
ANIOS OXI'ZYME, ANIOXYDE 1000 Basic UDI-DI 359761LA2B443DLIXL	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate number 31390 rev. 21 NB 0459
ANIOXYDE 1000 LD Basic UDI-DI 359761LA2B443ALIX5	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate number 31390 rev. 21 NB 0459
ANIOXY-TWIN CONCENTRE Basic UDI-DI	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate number 31390 rev. 21 NB 0459

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
359761LA2B433DLIX9			
OPASTER'ANIOS Basic UDI-UDI 359761LA2B413DLIWK	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate number 31390 rev. 21 NB 0459
STERANIOS 2% Basic UDI-DI 359761LA2B403DLIW8	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate number 31390 rev. 21 NB 0459
WIP ANIOS SPOR ACTIVE Basic UDI-DI 359761LA2A462NLIZ4	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate number 31390 rev. 21 NB 0459

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
2024-04-09	1000172972	Initial issue