Notified Body Confirmation Letter Reference: C683402

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, DNV Product Assurance AS, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number NB 2460 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:

EKOM spol. s r. o.

Priemyselná 5031/18

92101 Piešťany

Slovak Republic

SRN Number: SK-MF-000002069

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB 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 the NB 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issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a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.

Place and date:
Høvik, 2024/04/24

For the issuing office:
DNV Product Assurance AS – Notified Body 2460
Veritasveien 1. 1363 Høvik, Norway

André Fernandes
Management Representative

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)

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 (under MDR application)	**MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)**	**If the MDR device is a substitute device, identification of the corresponding MDD device**	**MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification**
Dental suction equipment / 858601462000005L5 **Model:** **DO-M**	IIa	**Product name on the certificate: ASPINA – model DO-M** **(only name change of the model not a substitute device)**	**9905-2017-CE-CZS-NA-PS rev.2.0; DNV Product Assurance AS, 2460**
Dental compressors with suction unit / 858601462000003KZ **Models:** DUO DUO/M DUO 2 DUO 2V DUO 2/M DUO 2V/M	IIa	NA	**9905-2017-CE-CZS-NA-PS rev.2.0; DNV Product Assurance AS, 2460**
Dental compressors / 858601462000002KX **Models:** DK50 DK50B	IIa	NA	**9905-2017-CE-CZS-NA-PS rev.2.0; DNV Product Assurance AS, 2460**

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
DK50BS DK50-10Z DK50-10Z/M DK50-10S DK50-10S/M DK50 PLUS DK50 PLUS/M DK50 PLUS S DK50 PLUS S/M DK50 PLUS MOBILE DK50 PLUS/M MOBILE DK50 2V DK50 2V/M DK50 2VS DK50 2VS/M DK50 2V/50 DK50 2V/50/M DK50 2V/50S DK50 2V/50S/M DK50 2V MOBILE DK50 2V/M MOBILE DK50 2x2V/110 DK50 2x2V/110/M DK50 2x2V/110S DK50 2x2V/110S/M DK50 4VR/50 DK50 4VR/50/M DK50 4VR/50S DK50 4VR/50S/M DK50 2x4VR/110 DK50 2x4VR/110/M DK50 2x4VR/110S DK50 2x4VR/110S/M			
Medical compressors / 858601462000004L3 **Model:** DK50 DS **Brand names:** SLE 500S, C235, MD50 DS, AC50 DS **Model:** DK50 DE **Brand names:** SLE 500E, SLE 100, MD50 DE, AC50 DE	IIb	NA	**9904-2017-CE-CZS-NA-PS rev.2.0; DNV Product Assurance AS, 2460**

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Model: DK50 DI **Brand names:** MD50 DI, AC50 DI **Model:** AIR-550 (=Variant of DK50 DI)			

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 (under MDR 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 device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
NA	**NA**	**NA**	**NA**

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/04/24	C683402	Initial issue

Lack of fulfilment of conditions

The following may render this letter of confirmation invalid:

- Lack of compliance to the requirements of Regulation (EU) 2023/607.
- Significant changes to design or intended purpose of the devices.
- Changes in the quality system affecting production.
- Periodical audits not held within the timeframe.