

TÜV Rheinland LGA Products GmbH • 51105 Köln

FEELLIFE HEALTH INC.
Room 1903, Building A, No.9 Furong Road, Tantou Community, Songgang
Subdistrict, Bao'an District, Shenzhen,
518104, Guangdong,
P.R. China

Contact

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Date January 11, 2024

Notified Body Confirmation Letter

Reference. : 10924075

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 **TÜV Rheinland LGA Products GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **0197** 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:

FEELLIFE HEALTH INC.
Room 1903, Building A, No.9 Furong Road, Tantou Community, Songgang
Subdistrict, Bao'an District, Shenzhen,
518104, Guangdong,
P.R. China
SRN Number (if available): CN-MF-000000782

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 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 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided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 March 20, 2023 for the relevant devices.

TÜV Rheinland
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Nuremberg HRB 26013
VAT No.: DE 811835490

Chairman of the
Supervisory Board

Dr.-Ing. Michael Fübi

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:

- May 26, 2026 for Class III custom-made implantable devices
- December 31, 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)
- December 31, 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- December 31, 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

Samuel Qin
2024.01.11
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Certification body

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 or 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/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Portable Mesh Nebulizer Model: Air 360+ Basic UDI-DI: 69343253R06010107B8D	Class IIa	N/A	Certificate # HD 60147222 0001 NB #0197
Portable Mesh Nebulizer Model: mini Air 360+ Basic UDI-DI: 69343253R06010108B8G	Class IIa	N/A	Certificate # HD 60147222 0001 NB #0197
Portable Mesh Nebulizer Model: A5 Basic UDI-DI: 69343253R06010109A8H	Class IIa	N/A	Certificate # HD 60147222 0001 NB #0197
Portable Mesh Nebulizer Model: Air Pro Basic UDI-DI: 69343253R06010115P98	Class IIa	N/A	Certificate # HD 60147222 0001 NB #0197
Portable Mesh Nebulizer Model: Air Angel Basic UDI-DI: 69343253R06010112A7Z	Class IIa	N/A	Certificate # HD 60147222 0001 NB #0197

Device name or 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/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Portable Mesh Nebulizer Model: Air Force Basic UDI-DI: 69343253R06010119A8N	Class IIa	N/A	Certificate # HD 60147222 0001 NB #0197
Portable Mesh Nebulizer Model: Air Mask Basic UDI-DI: 69343253R06010120A7Y	Class IIa	N/A	Certificate # HD 60147222 0001 NB #0197
Portable Mesh Nebulizer Model: AeroCentre Basic UDI-DI: 69343253R06010121A83	Class IIa	N/A	Certificate # HD 60147222 0001 NB #0197
Portable Mesh Nebulizer Model: Air Q+ Basic UDI-DI: 69343253R06010117A8G	Class IIa	N/A	Certificate # HD 60147222 0001 NB #0197
Portable Mesh Nebulizer Model: Air Bee Basic UDI-DI: 69343253R06010109V9T	Class IIa	N/A	Certificate # HD 60147222 0001 NB #0197
Portable Mesh Nebulizer Model: Air Garden Basic UDI-DI: 69343253R06010113G8G	Class IIa	N/A	Certificate # HD 60147222 0001 NB #0197
Portable Mesh Nebulizer Model: Air Pro II Basic UDI-DI: 69343253R06010115B8C	Class IIa	N/A	Certificate # HD 60147222 0001 NB #0197
Portable Mesh Nebulizer Model: Air Pro III Basic UDI-DI: 69343253R06010115C8E	Class IIa	N/A	Certificate # HD 60147222 0001 NB #0197
Portable Mesh Nebulizer Model: Aerogo Basic UDI-DI: 69343253R06010109F8T	Class IIa	N/A	Certificate # HD 60147222 0001 NB #0197
Portable Mesh Nebulizer Model: Air Plus Basic UDI-DI: 69343253R06010116P9B	Class IIa	N/A	Certificate # HD 60147222 0001 NB #0197
Portable Mesh Nebulizer Model: AeroCentre+	Class IIa	N/A	Certificate # HD 60147222 0001 NB #0197

Device name or 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/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Basic UDI-DI: 69343253R06010121C87			
Portable Mesh Nebulizer Model: Air Kids	Class IIa	N/A	Certificate # HD 60147222 0001 NB #0197
Basic UDI-DI: 69343253R06010122A86			
Portable Mesh Nebulizer Model: Air ICU	Class IIa	N/A	Certificate # HD 60147222 0001 NB #0197
Basic UDI-DI: 69343253R06010125A8F			
Portable Mesh Nebulizer Model: Air Pro VIII	Class IIa	N/A	Certificate # HD 60147222 0001 NB #0197
Basic UDI-DI: 69343253R06010113B86			
Portable Mesh Nebulizer Model: Air Pro IX	Class IIa	N/A	Certificate # HD 60147222 0001 NB #0197
Basic UDI-DI: 69343253R06010126A8J			
Portable Mesh Nebulizer Model: Air Mask II	Class IIa	N/A	Certificate # HD 60147222 0001 NB #0197
Basic UDI-DI: 69343253R06010120B82			
Portable Mesh Nebulizer Model: Air Plus 2	Class IIa	N/A	Certificate # HD 60147222 0001 NB #0197
Basic UDI-DI: 69343253R06010116B8F			
Portable Mesh Nebulizer Model: Air Mask D	Class IIa	N/A	Certificate # HD 60147222 0001 NB #0197
Basic UDI-DI: 69343253R06010120R92			

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 or 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/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
2024/01/11	10924075	Initial issue