POLISH CENTRE FOR
TESTING AND CERTIFICATION
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BM.433.0075.2023/BM.433.0120.0125.2024/ KW/MC/2024/0450 Warsaw, 04.11.2024

DERMOAROMA ITALY SRL

VIA DEI PIRENEI 1, 00144 ROMA, ITALY

Notified Body Confirmation Letter

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, Polish Centre for Testing and Certification, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1434 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:

DERMOAROMA ITALY SRL
VIA DEI PIRENEI 1
00144 ROMA
ITALY

SRN Number: IT-MF-000034895

The devices covered by the formal application and the written agreement mentioned above are identified in the Table 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.

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,

Tomasz Koeber

Tomasz Koeber

Head of Medical Device Certification Department

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**
HYALURONIC ACID INTRADERMAL FILLER **Basic UDI-DI:** **0759005146618 VOLOMIS STRONG** **0759005146625 VOLOMIS MEDIUM** **0759005159052 VOLOMIS SOFT** **0759005159076 VOLOMIS BODY**	Class III	HYALURONIC ACID INTERDERMAL FILLER Brand name: Volomis Soft, Volomis Medium, Volomis Strong	Certificate 1434-MDD-313/2021; 1434-MDD-314/2021 NB 1434
DPGPRP **Basic UDI-DI:805658595PRPTUBESX5** **Brand names: D-PRP, DERMOREGEN PRP, MEDICAESTHETICS-PRP, MESOAROMA-PRP, TIREG PLUS**	Class III	Medical device for preparation of Autologous platelet-rich plasma (P.R.P.)	Certificate 0425-MED-003692-00 NB 1434
CELL RENEW **Basic UDI-DI:805658595PEELINGSYSTEM9Z**	Class III	Skin Regenerating Solution Through Peeling	Certificate 0425-MED-004441-00 NB 1434

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Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
29.03.2024	BM.433.0075.2023/KW/MC/2024/0127	Initial issue
24.07.2024	BM.433.0075.2023/BM.433.0120.0125.2024/ KW/MC/2024/0340	Update of document – add medical devices PRP and Cell Renew under surveillance during transition period
04.11.2024	BM.433.0075.2023/BM.433.0120.0125.2024/ KW/MC/2024/0450	Update of document – DPGPRP brand names