



CERTIFICATE

EC Certificate No. 1434-MDD-313/2021
EC Design-examination
Directive 93/42/EEC concerning medical devices

Polish Centre for Testing and Certification certifies
that the documentation submitted by:

DERMOAROMA ITALY SRL

PIAZZA EUCLIDE N.2 ROME
00197 ROME, ITALY

related to the medical device, class III

HYALURONIC ACID INTERDERMAL FILLER

Brand name: Volomis Soft, Volomis Medium, Volomis Strong

was examined in accordance with Annex II (Section 4) to Directive 93/42/EEC (as amended) implemented into
Polish law, as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 18.05.2021 to 27.05.2024

The date of issue of the Certificate: 18.05.2021

The date of the first issue of the Certificate: 18.05.2021



Issued under the Contract No. MD-02/2021
Application No: 391/2021
Certificate bears the qualified signature.
Warsaw, 18/05/2021
Module H1

Vice-President



CERTIFICATE

EC Certificate No. 1434-MDD-314/2021
Full Quality Assurance System
Directive 93/42/EEC concerning medical devices

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

DERMOAROMA ITALY SRL

PIAZZA EUCLIDE N.2 ROME
00197 ROME, ITALY

for the design, manufacture and final inspection of
medical devices, class III

HYALURONIC ACID INTERDERMAL FILLER

Brand name: Volomis Soft, Volomis Medium, Volomis, Strong

complies with requirements of Annex II (excluding Section 4) to Directive 93/42/EEC (as amended)
implemented into Polish law, as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 18.05.2021 to 27.05.2024

The date of issue of the Certificate: 18.05.2021

The date of the first issue of the Certificate: 18.05.2021



Issued under the Contract No. MD-02/2021
Application No: 391/2020
Certificate bears the qualified signature.
Warsaw, 18/05/2021
Module H2/3/4/5

Vice-President



Polskie Centrum Badań i Certyfikacji S.A.

BM.433.0100.2022.1525.JMM

Warsaw, 17.10.2022 r.

**DERMOAROMA ITALY SRL
VIA DEI PIRENEI N.1,
00144, ROME**

To Whom It May Concern:

Polish Centre for Testing and Certification certifies that information in EC certificates no. 1434-MDD-313/2021 and 1434-MDD-314/2021 was updated by change of legal site address: VIA DEI PIRENEI N.1, 00144, ROME and addition of new brand names: **HYALURONIC ACID FILLER VOLOMIS BODY HARD** and **HYALURONIC ACID FILLER VOLOMIS BODY SOFT** for a medical devices class III **HYALURONIC ACID INTERDERMAL FILLER VOLOMIS STRONG** and **VOLOMIS SOFT** manufactured by DERMOAROMA ITALY SRL, VIA DEI PIRENEI N.1, 00144, Rome, Italy. Implementation of the change does not represent a significant change in design or intended purpose under MDR 2017/745 Article 120(3) and the related certificates no. 1434-MDD-313/2021 and 1434-MDD-314/2021 issued 18.05.2021 remains valid until 27.05.2024.

Sincerely,

Director of Medical Devices Certification Department

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