

EU Declaration of Conformity

Codice DCO

Rev.01 del 25.05.2023

EU Declaration of Conformity

MANUFACTURER Italfarmacia S.r.l.

Via di Tor Sapienza, 7 - 00155 Roma

Telefono: 06.45441800 Fax: 06.45441801

Unique registration number: IT-MF-000013116

NOTIFIED BODY Istituto Superiore di Sanità (ON 0373)

Viale Regina Elena, 299 - 00161 Roma

MEDICAL DEVICE INFINI V2

INTENDED USE Sterile, pyrogenic-free

and injectable medical device for intradermal microinjection, indicated in the prevention and treatment of skin damage from free radicals and in the treatment of skin damage, such as pigmentation and dehydration

CLASS AND RULE OF CLASSIFICATION

Class III implantable -

Rule 8

CE MARKING PROCEDURE

Annex IX (Chapters I - II - III) - EU Regulation 2017/745

PRODUCT CODE ITF003/u

805571533ITF0038Z

BASIC UDI-DI

CE MARKING CERTIFICATE Certificate number Review status Expire date

CSQ 0006-23 Rev.39 of 03.05.2024 02.03.2028

CVD 0013-23 Rev. 08 of 03.05.2024 02.03.2028



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The manufacturer Italfarmacia S.r.I. declares under its sole responsibility that the product identified above and subject of this declaration complies with the general performance and safety requirements set out in Annex I of EU Regulation 2017/745. The technical documentation has been drawn up according to the provisions of Annexes II and III of the aforementioned EU Regulation 2017/745.

Common specification with respect to which conformity is claimed: Not available.

Rome, date 14/05/2024

Italfarmacia S.r.l.

Legal Retimene pative Il legale raphresentante Mario Mario della raphresentante