



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 V1

INTENDED USE Sterile, pyrogenic-free
and injectable medical
device for intradermal
microinjection, indicated
in the prevention and
treatment of skin and
epidermal 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 ITF004/d

BASIC UDI-DI 805571533ITF00493

**CE MARKING
CERTIFICATE**

<i>Certificate number</i>	<i>Review status</i>	<i>Expire date</i>
CSQ 0006-23	Rev.38 of 03.05.2024	02.03.2028
CVD 0011-23	Rev.08 of 03.05.2024	02.03.2028

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The manufacturer Italfarmacia S.r.l. 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 16/05/2024

Italfarmacia S.r.l.
Italfarmacia S.r.l.
Legal Representative
Il legale rappresentante
Maurizio Marchetti