




EU Declaration of Conformity

**Codice
DCO**
Rev.01 del 16.05.2023

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 VE		
INTENDED USE	Sterile, pyrogenic-free and injectable medical device for intra-dermal microinjection, indicated in the prevention and treatment of facial skin damage, such as dehydration and pigmentation		
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	INFINI VE ITF001/u		
BASIC UDI-DI	805571533ITF0018V		
CE MARKING CERTIFICATE	<i>Certificate number</i>	<i>Review status</i>	<i>Expire date</i>
E	CSQ 0006-23	Rev.36 of 03.05.2024	02.03.2028
	CVD 0010-23	Rev.09 of 03.05.2024	02.03.2028

	EU Declaration of Conformity	Codice DCO Rev.01 del 16.05.2023
---	-------------------------------------	--

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
legale rappresentante
Mario Marchetti

