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 V BODY
INTENDED USE	Injectable medical device to be used for intradermal microinjection, indicated in the treatment of skin damage
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	ITF002/t
BASIC UDI-DI	805571533ITF0028X

CE MARKING CERTIFICATE	***Certificate number***	***Review status***	***Expire date***
	CSQ 0006-23	*Rev.37 of 03.05.2024*	*02.03.2028*
	CVD 0009-23	*Rev.05 of 03.05.2024*	*02.03.2028*

italfarmacia LABORATORI	**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* 14/05/2024

Italfarmacia S.r.l.

Legal Representative

Il legale rappresentante

Mario Marchetti