

This statement has been prepared in accordance with the provisions of NB-MED S/01/99 "Declaration of Conformity" and is released according to the total responsibility of the Manufacturer mentioned below.

DECLARATION OF CONFORMITY

MANUFACTURER: PAOLO GOBBI FRATTINI S.R.L.
I-23030 TOVO DI S. AGATA (SO), VIA PROVINCIALE 8

MEDICAL DEVICE:

SCC003 – "Liquid for the preservation of corneal grafts in hypothermic conditions up to 14 days"

CODES:

Product name	Packaging size	Reference number
iRestore Conservation, sterile	20 mL	SCC003.20
	30 mL	SCC003.30
	40 mL	SCC003.40

COMMERCIAL NAME: iRestore Conservation, sterile

CLASSIFICATION: Class IIa

We hereby declare that the mentioned medical device satisfies the essential requisites of safety, listed on MDD 93/42/CEE (DL. Nr. 46 del 24-02-97) as modified on Directive 47/2007/CE transposed by legislative decree 37/2010 and the requirements of the applicable rules.

The Technical File containing all the documentation required by MDD 93/42/CEE as modified on Directive 47/2007/CE transposed by legislative decree 37/2010 is located at Paolo Gobbi Frattini S.r.l. at disposal of Competent Authorities, Notified Body and local Health Authorities for at least 10 years.

STANDARDS:

IP corrente Ed.
EP corrente Ed.
ISO 10993-1
ISO 9001:2015; ISO 13485:2016

Reference number of CE certificate: QPZ-1922-19 of 21.09.2020 released by the Notified Body, Istituto Superiore di Sanità (ON 0373) - Viale Regina Elena 299, 00161 Roma (IT)

Tovo di S.Agata, 21.09.2020

The legal representative

Paolo Gobbi Frattini

innofamily since 70's

PAOLO GOBBI FRATTINI S.r.l. Unipersonale

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P.IVA IT 09131170962 - Cap.Soc. I.V. € 100.000,00 - paologobbifrattinisrl@pec.it
BANKACCOUNT: Banca Popolare di Sondrio – branch of Sondalo (SO)
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