

DECLARATION OF CONFORMITY

I, Luigi Mercuri, CEO of D.M.G. ITALIA SRL, a corporation duly organized and existing under the laws of Italy, with its Head Office in via Laurentina Km. 26.700 – 00071 Pomezia, Rome - Italy, registered at n° 773371 in the “Directory of Enterprises” of the Chamber of Commerce of Rome”, hereby

DECLARE

that our product

“Soluzione Oftalmica ad Azione Osmotica, Sterile (*Ophtalmic Solution with Osmotic Action, Sterile*)”

a Medical Device class IIb,

- is in compliance with the essential requirements of Annex I of Council Directive 93/42/EEC of 14 June 1993;
- is manufactured according to Annex II excluding (4) of Council Directive 93/42/EEC and subsequent modifications and integrations;
- was notified with the commercial name of **Terso**.

To confirm the above statement, I am enclosing the copy of the following document:

- **EC Declaration of Conformity Full Quality Assurance System – Document n° QCT 0081-18/17-18**, issued on 22.03.2018 by Istituto Superiore di Sanità, Notified Body n. 0373.

D.M.G. Italia srl



Luigi Mercuri
Amministratore Unico/CEO

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Pomezia, Rome (Italy), 13/05/2021

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