DECLARATION OF CONFORMITY

Name and address of the manufacturer:

Optima Medical Swiss AG
Bundesstrasse 7
6300 Zug
Switzerland

Name and address of the EU representative:
Optima Sanità S.r.l.
Viale della Stazione 5
39100 Bolzano (BZ)
Italy

We declare under our sole responsibility that the medical device, manufactured during the term mentioned below,

Brand name and Product:

The eye doctor Intensive Relief Eye Mist
liposomal eye spray DexOKM

of class IIa according to Art. 9 (1) in conjunction with Annex IX, chapter III, Section 2.1, rule 5 of Directive 93/42/EEC meets all the provisions which apply to it in accordance to Art 120 (3d) and (3e) of Regulations (EU) 2017/745 and our conformity assessment procedure in compliance to Annex VII of the Directive 93/42/EEC.
The conformity assessment procedure was performed in accordance with appendices V and VII of Directive 93/42/EEC involving the following notified bodies:

Notified Body:
MEDCERT GmbH
Pilatuspool 2
20355 Hamburg
Germany

Identification Number:	0482
Process No.:	QS – 7086
Certificate No.:	7086GB414180727
Validity:	31.12.2028 in accordance to Art 120 (2) of Regulations (EU) 2017/745

optima
Medical Swiss AG

According to Art. 120 (3a) of Regulations (EU) 2017/745 this declaration is valid until 31 December 2028 – unless earlier withdrawn by us.

28.07.2023
date

Michael Kroll
governing board / PRRC