

EU Declaration of Conformity

Comoframe SRL

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In its capacity as the manufacturer, hereby declares, under its sole responsibility, that the optical frame

Model Name: NEWBORN

Model Colors Codes: NB01, NB02, NB03,

is a class I medical device (Rule 1 Chapter III of Annex VIII of (EU) Regulation 2017/745), which is intended for use in connection with, in the manufacturing of eyeglasses, ophthalmic lenses for correcting vision problems.

Also Declares

that it is in conformity with the provisions of (EU) Regulation 2017/745 on Medical Devices and with the standard EN ISO 12870:2018

Unique manufacturer registration number : Not Applicable

Basic UDI-DI: 805759293AQ02100202RZ

Sesto San Giovanni, May 16th, 2021

Luca Trovati
Managing Director

