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Name of manufacturer Eschenbach Optik GmbH

Fürther Straße 252, 90429 Nürnberg

Germany

Single Registration Number (SRN) **DE-MF-000007711**

We declare under sole responsibility that the product

Name of product optaro 16533

Basic UDI-DI 4064158ELECTRONVISAIDSDQA

Nomenclature GMDN Code 30045

EMDN Code Y210699

Risk class Class I – non sterile, no measuring function

Conformity assessment procedure pursuant to article 52 (7) for medical devices

conforms with the following regulations:

Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices

Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

Directive 94/62/EC on packaging and packaging waste

Regulation (EU) 2023/1542 of the European Parliament and of the Council concerning batteries and waste batteries

Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment

Directive 2012/19/EU on waste electrical and electronic equipment (WEEE)

Directive 2014/30/EU on the approximation of the Laws of Member States relating to electromagnetic compatibility

Directive 2014/35/EU on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits (codified version)

Directive 2014/53/EU on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment

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We operate a systematic procedure to monitor the product after placing it on the market.

Nuremberg, 12.09.2024

Place and date of issue

sgd. M. Anke
Name,
Matthias Anke
Managing Director

sgd. A. Jahnke
Name,
Andreas Jahnke
MDR Responsible Person