



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 **electronic visual aids / Models see Annex**

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

Directive 2006/66/EC on batteries and accumulators and waste batteries and accumulators as regards placing batteries and accumulators on the market

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 harmonization of the laws of Member States relating to electrical equipment designed for use within certain voltage limits (codified version)



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

Nuremberg, 18.08.2021

Place and date of issue

sgd. M.Anke

**Name,
Matthias Anke**
Managing Director

sgd. A. Jahnke

**Name,
Andreas Jahnke**
MDR Responsible Person



Annex

Model-No.	Name
16502	smartlux DIGITAL
16511	mobilux DIGITAL Touch HD
16521	visolux DIGITAL HD
16551	visolux DIGITAL XL FHD
16591	vario DIGITAL FHD
165916	vario DIGITAL FHD Advanced
1659161	vario DIGITAL FHD Advanced TB
1659162	vario DIGITAL FHD Advanced B
1659163	vario DIGITAL FHD Advanced T
16592	vario DIGITAL 22 FHD
165922	vario DIGITAL 22 FHD Advanced
1659221	vario DIGITAL 22 FHD Advanced TB
1659222	vario DIGITAL 22 FHD Advanced B
1659223	vario DIGITAL 22 FHD Advanced T