1) Manufacturer

Digitally signed by Pereteatco Alina
Date: 2023.04.24 07:50:07 EEST
Reason: MoldSign Signature
Location: Moldova

Manufacturer name : CILITA Ltd
Address: Russia, Ryazan, 390044, Moscovskoye Shosse, 20. office 702.
Tel/fax: +7 (4912) 77-96-78
e-mail: sales@cilita.com
web site: cilita.com

2) Authorized representative on the territory of European Economic Community (EU REP)

The name of European Authorized representative name and address:
Arazy Group GmbH
PHONE: +49 69 95932-5090
FAX: +49 69 95932-5200
GERMANY@ARAZYGROUP.COM
The Squaire 12, Am Flughafen, 60549 Frankfurt am Main, Germany

3) Product

PRODUCT NAME: OPHTHALMIC CILITA INSTRUMENTS
Type/model/number: Bladeholder, Ophthalmic Caliper, Corneoscleral Punch (Pliers), Ophthalmic Curette, Ophthalmic Depressor, Eye Probe, Forceps for anterior and posterior chamber, Forceps, Clamps, Ophthalmic Handle, Ophthalmic Hook, Injector, Irrigation / Aspiration Handle, Lens Manipulator, Ophthalmic Marker, Ophthalmic Needleholder, Ophthalmic Retractor, Scissors for anterior and posterior chamber, Ophthalmic Scissors, Ophthalmic Spatula, Screw Eye Speculum

Risk Class/ Rule: Class I / Rule 6
GMDN 13486

4) Conformity with “Directives” , “Standards and “Guidance MEDDEVs ” :

The above-mentioned product is in conformity with the requirements and provisions of the:

- Regulation (EU) 2017/745, MDR
- EN ISO 15223-1:2016
- EN 1041:2008
- EN ISO 14971:2012
- EN ISO 13485:2016
- EN ISO 10993-1:2009

5) Conformity procedure

The device is the subject of procedure described in Annex VII of the Regulation (EU) 2017/745, MDR for medical devices (technical documentation).

Ryazan , Russia Date: 20.09.2021

General Manager
CILITA Ltd
D.Iakovlev