

EC Declaration of Conformity

Manufacturer Name: RefLab Aps

Manufacturer Address: Ole Maaløes Vej 3, COBIS
2200 Copenhagen N
DK-Denmark

SRN (Single Registration Number): DK-MF-000021844

Basic UDI-DI: 574400328OPAHN

Name of the Device(s): OPA Disc 25 mg, 20 pcs, OPA Disc 25 mg, 100 pcs, OPA Disc 5 mg, 10 pcs

Catalogue number(s): RLA708, RLA708XL, RLR013

Product code: W0201020285

Classification: IVDR, Class A

Notified Body name: N/A

Notified Body Address: N/A

Notified Body Identification number: N/A

Conformity assessment route: RefLab Aps uses the following procedures for the CE-labeling of their products according to the Regulation IVDR 2017/746:

Class A: EC conformity declaration according to Annex IV.

This declaration of conformity is issued under the sole responsibility of RefLab Aps. We hereby declare that the in-vitro diagnostic medical device(s) specified above meet the provision of the Regulation (EU) IVDR 2017/746. This declaration is supported by the ISO 13485 Quality Management System approval issued by DQS. All supporting documentation is retained at the premises of the manufacturer.

Signature:



Lise Bo
Quality Manager

Place and date (dd.mm.yyyy) of issue:

Copenhagen, 20.05.2022

RefLab ApS