

# ***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:** 574400328RINSECH

**Name of the Device(s):** Detergent for Histareader, Acidic Clean for Histareader

**Catalogue number(s):** RLA705, RLA709

**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**