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:	574400328READER8M
Name of the Device(s):	Histareader™501, Histareader™501-1
Catalogue number(s):	RLA501, RLA501-1
Product code:	W0201020280
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