EC Declaration of Conformity

Manufacturer Name:	RefLab Aps
Manufacturer Address:	Kanalholmen 1, 2.th DK-2650 Hvidovre Denmark
SRN (Single Registration Number):	DK-MF-000021844
Classification:	IVDR, Class A
Notified Body name:	N/A
Notified Body Address:	N/A
Notified Body Identification number:	N/A

Reflab Aps hereby declares conformity to REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices for the following In Vitro Diagnostic Devices:

Art. no	Name of device	Basis UDI-DI	UDI
RLA501	Histareader501	574400328READER8M	05744003280018
RLA501-1	Histareader501-1		05744003280025
v3.0-0612	Software (501) v3.0-0612	574400328SOFTWE5	05744003280032
v12-0612	Software (501-1) v12-0612		05744003280056
RLA216	Calibration plate, single plate	574400328CALIB46	05744003280070
RLA216.10	Calibration plate, box of 10		05744003280087

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 Bureau Veritas. All supporting documentation is retained at the premises of the manufacturer.

Signature:

Randi Lundberg
COO

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

Hvidovre, 17-Nov-2023