REFLAB
Member of R-Biopharm Group

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, Rule 5, 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
RLA705	Detergent for Histareader	574400328RINSECH	05744003280094
RLA700	Reagent Kit	574400328REAGK8U	05744003280117
RLR006	Pipes buffer, 100 mL	574400328PIPESBP	05744003280124
RLA706.900	Pipes buffer, 900 mL		05744003280131
RLA706.1000	Pipes buffer, 1 L		05744003280148
RLR007W.200	Wash buffer, 200 mL	574400328WASHDP	05744003280155
RLR007W.5	Wash buffer, 5 L		05744003280162
RLR007S.50	Wash buffer concentrate, 50 mL		05744003280186
RLR007S.10	Wash buffer concentrate, 10 mL		05744003280179
RLA708	OPA Disc, 25 mg	574400328OPAHN	05744003280193
RLA708X	OPA Disc, 25 mg		05744003280209
RLR013	OPA Disc, 5 mg		05744003280216
RLA702	Diluent, 1 L	574400328DILUENTGG	05744003280230
RLR009	Diluent, 10 mL		05744003280223
RLA703	Stop reagent, 1 L	574400328STOPFW	05744003280254
RLR011	Stop reagent, 100 mL		05744003280247
RLR016	Stripping buffer, 1 L	5744003280STRIP6M	05744003280278
RLA701	Stripping buffer, 100 mL		05744003280261
RLA704	Lysis reagent, 10 mL	5744003280LYSIS5N	05744003280285
RLR041	Preparation vial	5744003280IL34Q	05744003280308
RLA500	Preparation vial		05744003280315
RLR004	IL-3, 0,1 µg		05744003280292
RLA216	Calibration plate, single plate	574400328CALIB46	05744003280070
RLA216.10	Calibration plate, box of 10		05744003280087

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

Signature:

Henrik Christensen
Chief Executive Director

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

Hvidovre, 22-Oct-2024

RefLab ApS
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