CERTIFICATE

EC No 1434-IVDD-222/2019
EC Design-Examination

Directive 98/79/EC on in vitro diagnostic medical devices

Polish Centre for Testing and Certification certifies
that manufactured by:

Grifols Diagnostic Solutions Inc.

4560 Horton Street
Emeryville, California 94608, USA

in vitro diagnostic medical devices
List A

Products list in attachments: 1

in terms of design documentation, comply with requirements of Annex IV section 4 to Directive 98/79/EC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC.

Validity of Certificate: from 26.04.2019 to 13.06.2022

The date of issue of the Certificate: 26.04.2019

Digitally signed by Ceaicovschi Tudor
Date: 2022.11.09 16:49:32 EET
Reason: MoldSign Signature
Location: Moldova

CE 1434

mgr Anna Wyroba
Vice-President

Application No: 617/2019
Module: H6

Certificate No **1434-IVDD-222/2019**
Issued under the Contract No MD-92/2019
Bears the PCBC hologram.
Warsaw, 26.04.2019

ANNEX 1 TO CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-IVDD-222/2019

The products detailed below are covered under the scope of this certificate:

Procleix Ultrio Elite Assay - 303330 / 303715

Procleix Ultrio Elite HIV, HCV and HBV Discriminatory Probe Reagents - 303334

Procleix Ultrio Elite Target Enhancer Reagent - 303331 / 303722

Procleix Ultrio Elite Negative Calibrators - 303333

Procleix Ultrio Elite Positive Calibrators - 303332

Procleix Ultrio Elite Assay Calibrators Kit - 303719 / 303723

CE 1434

mgr Anna Wyroba
Vice-President

Annex 1 to certificate No. **1434-IVDD-222/2019**
Issued under the Contract No. MD-92/2019
Bears the PCBC hologram.
Warsaw, 26.04.2019