



CERTIFICATE

EC No 1434-IVDD-223/2019
Full Quality Assurance System

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

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

Grifols Diagnostic Solutions Inc.

4560 Horton Street
Emeryville, California 94608, USA

for the design, manufacture and final inspection of in vitro diagnostic medical devices
List A

Products list in attachments: 1

complies with requirements of Annex IV excluding section 4 and 6 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



Application No: 617/2019
Module: H7


mgr Anna Wyroba
Vice-President



Certificate No **1434-IVDD-223/2019**
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-223/2019

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




mgr Anna Wyroba
Vice-President



Annex 1 to certificate No. **1434-IVDD-223/2019**
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Warsaw, 26.04.2019