



CERTIFICATE

EC Certificate No. 1434-IVDD-107/2022

**EC Design-examination
Directive 98/79/EC concerning
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,
UNITED STATES**

i.e. *in vitro* diagnostic medical devices
List A

The list of medical devices covered by this certificate is provided in the annex 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 the Certificate: from 25.04.2022 to 27.05.2025

The date of issue of the Certificate: 25.04.2022

The date of the first issue of the Certificate: 26.04.2019



Issued under the Contract No. MD-181/20219
Application No: 580/2019
Certificate bears the qualified signature.
Warsaw, 25/04/2022
Module H6/V1

Aleksandra Digitally signed
Kostrzewa by Aleksandra
Kostrzewa
President