



CERTIFICATE

EC Certificate No. 1434-IVDD-108/2022
Full Quality Assurance System
Directive 98/79/EC concerning
***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,
UNITED STATES

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

*The list of medical devices covered by this certificate is provided in the annex 1 to EC Design-
examination Certificate No. 1434-IVDD-107/2022*

complies with requirements
of Annex IV (excluding Section 4, 6) 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-181/2019
Application No: 580/2019
Certificate bears the qualified signature.
Warsaw, 25/04/2022
Module H7

Aleksandra
Kostrzewa

Digitally signed by
Aleksandra Kostrzewa

President