CERTIFICATE

EC Certificate No. 1434-IVDD-144/2022

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:

Tulip Diagnostics (P) Ltd.

Gitanjali, Tulip Block, Dr. Antonio Do Rego Bagh, Alto Santacruz, Bambolim Complex P.O., Goa - 403202, INDIA

Manufacturing unit address:

Plot No. 92/96, Phase II-C, Verna Industrial Estate, Verna, Goa - 403722, INDIA

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

The list of medical devices covered by this certificate is provided in the annex no. 1

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 17.05.2022 to 31.01.2025

The date of issue of the Certificate: 17.05.2022

The date of the first issue of the Certificate: 31.01.2020

CE 1434

Issued under the Contract No. MD-96/2019
Application No: 295a/2018
Certificate bears the qualified signature.
Warsaw, 17/05/2022
Module H7

Aleksandra Kostrzewa
Digitally signed by Aleksandra Kostrzewa
President

ANNEX no. 1 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-IVDD-144/2022

List of medical devices covered by the certificate:

Matrix AHG (Coombs) Test Card
Matrix Coombs Anti-IgG Card
INVITROGEL AHG (Coombs)
INVITROGEL IgG (Coombs)

CE 1434

Issued under the Contract No. MD-96/2019
Application No: 295a/2018
Certificate bears the qualified signature.
Warsaw, 17/05/2022

President

CERTIFICATE

EC Certificate No. 1434-IVDD-145/2022

EC Design-examination
Directive 98/79/EC concerning
***in vitro* diagnostic medical devices**

Polish Centre for Testing and Certification certifies
that manufactured by:

Tulip Diagnostics (P) Ltd.
Gitanjali, Tulip Block, Dr. Antonio Do Rego Bagh,
Alto Santacruz, Bambolim Complex P.O.,
Goa - 403202, INDIA

Manufacturing unit address:
Plot No. 92/96, Phase II-C, Verna Industrial Estate,
Verna, Goa - 403722, INDIA

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

The list of medical devices covered by this certificate is provided in the annex no. 1 and annex no. 2

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 17.05.2022 to 31.01.2025

The date of issue of the Certificate: 17.05.2022

The date of the first issue of the Certificate: 31.01.2020

CE 1434

Issued under the Contract No. MD-96/2019
Application No: 294a/2018
Certificate bears the qualified signature.
Warsaw, 17/05/2022
Module H6/V1

Aleksandra Kostrzewa
Digitally signed by Aleksandra Kostrzewa
President

ANNEX no. 1 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-IVDD-145/2022

List of medical devices covered by the certificate:

ERYSCREEN
ERYSCREEN PLUS
ERYSCREEN TOTAL
ERYCLONE Anti-A Monoclonal
ERYCLONE Anti-B Monoclonal0
ERYCLONE Anti-A, B Monoclonal
ERYCLONE Anti-D (Rho) (IgM) Monoclonal
RHOFINAL Anti-D (Rho) (IgM + IgG) Monoclonal
ERYCARD 2.0 Blood Grouping Card for ABO/Rho (D) Forward Grouping with Autocontrol
Matrix ABO/Rho (D) Forward and Reverse Grouping Card with Autocontrol
Matrix ABO/Rho (D) Forward Grouping Confirmation Card
Matrix ABO/Rho (D)/AHG Neonate Group Card
Matrix Forward Grouping and Cross Match Card
Matrix Forward Grouping Card with Anti-D (VI+)
Matrix Forward Grouping DAT Card
Matrix Rh Phenotype Card with Anti-K
Matrix Rh Phenotype Card with Anti-D

CE 1434

Issued under the Contract No. MD-96/2019
Application No: 294a/2018
Certificate bears the qualified signature.
Warsaw, 17/05/2022

Aleksandra Kostrzewa
Digitally signed by Aleksandra Kostrzewa
President

ANNEX no. 2 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-IVDD-145/2022

List of medical devices covered by the certificate:

INVITROGEL ABO REVERSE
INVITROGEL ABO CROSSMATCH
INVITROGEL ABD
INVITROGEL ABO DII DAT
INVITROGEL ABO NEWBORN
INVITROGEL RH PHENO I+K
INVITROFLOW ABD(VI-)
INVITROCLONE ANTI-A
INVITROCLONE ANTI-B
INVITROCLONE ANTI-AB
INVITROCLONE ANTI-D IgM
INVITROCLONE ANTI-D IgM+IgG

CE 1434

Issued under the Contract No. MD-96/2019
Application No: 294a/2018
Certificate bears the qualified signature.
Warsaw, 17/05/2022

Aleksandra Kostrzewa
Digitally signed by Aleksandra Kostrzewa
President

CERTIFICATE

EC Certificate No. 1434-IVDD-146/2022

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:

Tulip Diagnostics (P) Ltd.

Gitanjali, Tulip Block, Dr. Antonio Do Rego Bagh, Alto Santacruz, Bambolim Complex P.O., Goa - 403202, INDIA

Manufacturing unit address:

Plot No. 92/96, Phase II-C, Verna Industrial Estate, Verna, Goa - 403722, INDIA

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 no. 1 and annex no. 2 to EC Design-examination Certificate No. 1434-IVDD-145/2022

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 17.05.2022 to 31.01.2025

The date of issue of the Certificate: 17.05.2022

The date of the first issue of the Certificate: 31.01.2020

CE 1434

Issued under the Contract No. MD-96/2019
Application No: 294a/2018
Certificate bears the qualified signature.
Warsaw, 17/05/2022
Module H7

Aleksandra Kostrzewa
Digitally signed by Aleksandra Kostrzewa
President