

EC DECLARATION OF CONFORMITY

In accordance with Regulation (EU) 2017/746 of the European Parliament and of the Council

Manufacturer:

PZ CORMAY S.A.

22 Wiosenna Str.

05-092 Lomianki

Poland

Single Registration Number (SRN): PL-MF-000023053

We, PZ CORMAY S.A., declare that the following device:

Device name: LYSING REAGENT KX21 CN FREE

Device catalogue number: 8-877

Basic UDI-DI: 590751468-8777F

Device class: A

Classification rule: 5a

Intended use: LYSING REAGENT KX 21 CN FREE is intended to lyse of erythrocytes for hemoglobin release to allow further hemoglobin's assay on hematological analyzers: SYSMEX KX-21 and SYSMEX KX-21N. It prepares leukocytes for subpopulations differentiation process. It is only or in vitro diagnostics, for healthcare professional users.

complies with General Safety and Performance Requirements of the ANNEX I – Regulation (EU) 2017/746 of the European Parliament and of the Council and their Conformity Assessment has been made accordingly to the ANNEX IX – Regulation (EU) 2017/746 of the European Parliament and of the Council.

This Declaration of Conformity is issued under the sole responsibility of PZ CORMAY S.A.

Signature:

Anna Smolira



Person responsible for regulatory compliance of

PZ CORMAY S.A.

Signature:

Robert Wiśniewski



Person responsible for regulatory compliance of

PZ CORMAY S.A.

Place: Lublin

Date: 1 August 2022

PZ Cormay S.A.

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