



EU DECLARATION OF CONFORMITY

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

Manufacturer:

Orphée SA
19 chemin du Champ-des-Filles
CH-1228 Plan-les-Ouates / Geneva
Switzerland
Swiss Single Registration Number (CHRN):
CHRN-MF-20002396

Authorized representative:

PZ CORMAY S.A.
22 Wiosenna Str.
05-092 Lomianki
Poland
Single Registration Number (SRN):
PL-AR-000026245

We, Orphée SA, declare that the following device:

Device name: Mythic 18 Cyanide free Lytic solution

Device catalogue numbers: HM18-008-05, HM18-008-1

Basic UDI-DI: 764014248HM18-0082Z

Device class: A

Classification rule: 5a

Intended use: Mythic 18 Cyanide free Lytic solution is intended to lyse of erythrocytes for hemoglobin release to allow further hemoglobin's assay on hematological analyzer MYTHIC 18. It prepares leukocytes for subpopulations differentiation process. It is only for 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 Orphée SA.

Signature:

Anna Smolira

Person responsible for regulatory compliance
of Orphée SA

Signature:

Robert Wiśniewski

Person responsible for regulatory compliance
of Orphée SA

Place: Lublin

Date: 12 July 2023