Orphée

EC 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: CLEANER FOR MYTHIC 22

Device catalogue number: HM22-001-1

Basic UDI-DI: 764014248HM22-001YT

Device class: A

Classification rule: 5a

Intended use: CLEANER FOR MYTHIC 22 is intended to remove biological material's residues from the measurement system of the hematology analyzers: MYTHIC 22, MYTHIC 22AL, MYTHIC 60 and MYTHIC 70. 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