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: OnlyOne

Device catalogue number: HM22-002-1

Basic UDI-DI: 764014248HM22-002YV

Device class: A

Classification rule: 5a

Intended use: OnlyOne is intended to lyse of erythrocytes for hemoglobin release to allow further hemoglobin's assay on hematological analyzers: MYTHIC 22, MYTHIC 22AL, MYTHIC 60 and MYTHIC 70. 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