Orphée

EC DECLARATION OF CONFORMITY

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

Manufacturer:	**Authorized representative:**
Orphée SA	PZ CORMAY S.A.
19 chemin du Champ-des-Filles	22 Wiosenna Str.
CH-1228 Plan-les-Ouates / Geneva	05-092 Lomianki
Switzerland	Poland
Swiss Single Registration Number (CHRN):	Single Registration Number (SRN):
CHRN-MF-20002396	PL-AR-000026245

We, Orphée SA, declare that the following device:

Device name: MYTHIC 3CRP Diluent

Device catalogue number: HM3CRP-003-10, HM3CRP-003-20

Basic UDI-DI: 764014248HM3CRP-003CY

Device class: A

Classification rule: 5a

Intended use: MYTHIC 3CRP Diluent is intended to dilute blood samples before assay and to maintain appropriate environment during assay on hematology analyzer MYTHIC 3CRP. 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