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 CRP-L

Device catalogue number: HM3CRP-005-L0040, HM3CRP-005-L0075, HM3CRP-005-L0200

Basic UDI-DI: 764014248HM3CRP-005LWT

Device class: A

Classification rule: 5a

Intended purpose: MYTHIC 3CRP CRP-L reagent is intended to complete lysis of blood cells on hematological analyzer MYTHIC 3CRP. It prepares the sample for immune nephelometric measurement of CRP concentration. 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:	Signature:
Anna Smolira	Robert Wiśniewski
Person responsible for regulatory compliance of Orphée SA	Person responsible for regulatory compliance of Orphée SA

Place: Lublin

Date: 12 July 2023