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

Authorized representative:
PZ CORMAY S.A.
Wiosenna 22
05-092 Łomianki
Poland

Swiss Single Registration Number (CHRN):
CHRN-MF-20002396

Single Registration Number (SRN):
CH-MF-000050926

Single Registration Number (SRN):
PL-AR-000026245

Manufacturing site:
Shenzhen Dymind Biotechnology Co., Ltd.
1st, 2nd, 4th and 5th Floors, Area A, Building B, Yeming Mold Industrial Park, Genyu Road, Tianliao Community, Yutang Subdistrict Office,
Guangming District, Shenzhen 518132,
P.R. CHINA

We, Orphée SA, declare that the following device:

Device name: MYTHIC 3CRP Diluent
Basic UDI-DI code: 764014248HM3CRP-003CY
Device class: A
Conformity route: Self-declaration of conformity

Cat no.	Reagent name	Variants	Intended purpose
HM3CRP-003-10	MYTHIC 3CRP Diluent	10 l	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.
HM3CRP-003-20		20 l	

complies with the 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:
Joanna Stec

Person responsible for regulatory compliance of Orphée SA

Place: Lublin

Date: 9.01.2026