



## 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: Mythic 18-22 FLUSH-CLEANER**

**Device catalogue number: HM18-011-025**

**Basic UDI-DI: 764014248HM18-0112N**

**Device class: A**

**Classification rule: 5a**

**Intended use:** Mythic 18-22 FLUSH - CLEANER is intended for periodic and emergency cleaning of the hematology analyzers' measuring system. 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