EU Declaration of Conformity

Manufacturers Name:	Boule Medical AB
Manufacturers Address:	Domnarvsgatan 4 SE-16353 Spånga, Sweden
SRN (Single Registration Number):	SE-MF-000001911

Product information

Basic UDI-DI:	735004079A012YB
EMDN code	W010301

UDI-DI	Product code	Product name
7350040794043	1504122	Medonic M-serie Diluent 20L
7350040796283	1504460	Medonic M-series Diluent, RFID
7350040794050	1504123	Medonic M-series Lyse, 5L
7350040796290	1504461	Medonic M-series Lyse, RFID
7350040794067	1504128	Medonic M-series Dual-pack
7350040796337	1504465	Medonic M-serie DualPack, RFID

Risk Classification	Class A	According to Rule 5a
Intended purpose	Medonic M-series Diluent and Medonic M-series Lyse are accessories intended to be used in combination with Medonic M-series 3-part hematology analyzers to dilute and lyse blood cells and thereby enable the analyzer to count and classify platelets, red and white blood cells and measure the hemoglobin concentration. The reagents do not provide any results on their own and can only be used as consumables in combination with Medonic M-series analyzers.	
IVDR assessment route	CE marking under the sole responsibility of manufacturer, Self-assessment	

Table 1 – Products included in this Declaration of Conformity

Applicable European directives and regulations

Regulation/Directive	
EU 2017/746	In Vitro Medical Devices Regulation

Table 2 – Applicable regulations/directives

Boule Medical AB hereby declares that the medical device(s) listed in *Table 1* are in conformity with applicable requirements of the Directive/Regulation/s listed in *Table 2*.

This declaration of conformity is issued under the sole responsibility of and signed on behalf of Boule Medical AB

Spånga, 2022-05-13 — Jesper Söderqvist, CEO

Place and date of issue

Spånga, 2022-05-13 — Terese Wasell, PRRC

Place and date of issue