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:	735004079A016YK
EMDN code	W010301

UDI-DI	Product code	Product name
7350040796399	1504510	Medonic M51-D Diluent, 20L
7350040796405	1504511	Medonic M51-L1 Lyse, 200mL
7350040796412	1504512	Medonic M51-L2 Lyse, 500mL
7350040796429	1504514	Swelab Lumi-D Diluent, 20L
7350040796436	1504515	Swelab Lumi-L1 Lyse 200mL
7350040796443	1504516	Swelab Lumi-L2 Lyse, 500mL

Table 1 – Products included in this Declaration of Conformity

Risk Classification	Class A	According to Rule 5a
Intended purpose	Medonic M51-D Diluent/Swelab Lumi-D Diluent, Medonic M51-L1 Lyse/Swelab Lumi-L1 Lyse and Medonic M51-L2 Lyse/Swelab Lumi-L2 Lyse are accessories intended to be used in combination with the Medonic M51/Swelab Lumi analyzer 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 in combination with Medonic M51/Swelab Lumi analyzer	
IVDR assessment route	CE marking under the sole responsibility of manufacturer, Self-assessment	

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, 2022-06-27 — Jesper Söderqvist, CEO

Place and date of issue

Spånga, 2022-06-27 — Terese Wasell, PRRC

Place and date of issue