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:	735004079A009YN
EMDN code	W05010102

UDI-DI	Product code	Product name
7350040790250	1070030	Plastic Micropipettes 10x100
7350040790687	1070039	Micro pipette, plastic EDTA 1x100
7350040790694	1071049	Micro pipette, plastic EDTA 10x100

Table 1 – Products included in this Declaration of Conformity

Risk Classification	Class A	According to Rule 5c
Intended purpose	The specimen receptacle Boule MPA Micro Pipettes, Plastic, is a K2EDTA-coated capillary tube intended for In Vitro Diagnostic use for blood collection from a finger stick or a venous blood sample for direct insertion into the Micro Pipette Adapter (MPA) inlet of Medonic M-series and Swelab Alfa automated hematology analyzer series	
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, 2022-05-25 — Jesper Söderqvist, CEO

Place and date of issue

Spånga, 2022-05-25 — Terese Wasell, PRRC

Place and date of issue