

# EU Declaration of Conformity

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

## Product information

<b>Basic UDI-DI:</b>	735004079A005YE
<b>EMDN code</b>	W010301

UDI-DI	Product code	Product name
7350040790199	1504111	Boule Cleaning Kit 3 x 450 ml
7350040790205	1504112	Boule Enzymatic Cleaner 100mL
7350040794463	1504113	Boule Hypochlorite 2,0% Cleaner

Table 1 – Products included in this Declaration of Conformity

<b>Risk Classification</b>	Class A	According to Rule 5a
<b>Intended purpose</b>	<p>Boule Cleaning Kit is an accessory intended for cleaning and maintenance of Medonic M-series and Swelab Alfa hematology analyzers in a professional laboratory setting.</p> <p>Boule Enzymatic Cleaner is an accessory intended for cleaning and maintenance of Medonic M-series and Swelab Alfa hematology analyzers in a professional laboratory setting.</p> <p>Boule Hypochlorite 2,0% Cleaner is an accessory intended for cleaning and maintenance of Medonic M-series and Swelab Alfa hematology analyzers in a professional laboratory setting.</p>	
<b>IVDR assessment route</b>	CE marking under the sole responsibility of manufacturer, Self-assessment	

## Applicable European directives and regulations

<b>Regulation/Directive</b>
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, 2022-05-24  
Place and date of issue

  
Jesper Söderqvist, CEO

Spånga, 2022-05-24  
Place and date of issue

  
Terese Wasell, PRRC