

EU Declaration of Conformity

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| 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: | 735004079A010Y7 |
| EMDN code | W010301 |

| UDI-DI | Product code | Product name |
|---------------|--------------|-------------------------|
| 7350040791417 | 1504513 | Boule EasyCleaner, 50mL |

Table 1 – Products included in this Declaration of Conformity

| | | |
|------------------------------|--|----------------------|
| Risk Classification | Class A | According to Rule 5a |
| Intended purpose | Boule EasyCleaner is an accessory intended for regular cleaning and maintenance of Medonic M51/Swelab Lumi inlet and fluidic system. | |
| IVDR assessment route | CE marking under the sole responsibility of manufacturer, Self-assessment | |

Applicable European directives and regulations

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|---|
| 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,

2022-06-29

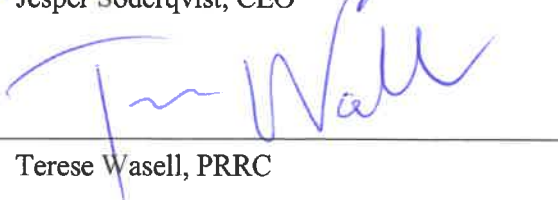
Place and date of issue


Jesper Söderqvist, CEO

Spånga,

2022-06-29

Place and date of issue


Terese Wasell, PRRC