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:	735004079A013YD
EMDN code	W010301

UDI-DI	Product code	Product name
7350040790175	1504124	Swelab AlfaDiluent, 900 cycles
7350040796306	1504462	Swelab AlfaDiluent, RFID
7350040790182	1504125	Swelab AlfaLyse, 900 cycles
7350040796313	1504463	Swelab AlfaLyse, RFID
7350040790304	1504127	Swelab Alfa ComboPack 200
7350040796320	1504464	Swelab Alfa ComboPack, RFID

Risk Classification	Class A	According to Rule 5a
Intended purpose	Swelab AlfaDiluent and Swelab AlfaLyse are accessories intended to be used in combination with Swelab Alfa 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 Swelab Alfa 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, May 23, 2022
Place and date of issue

Jesper Söderqvist, CEO

Spånga, May 23, 2022
Place and date of issue

Terese Wasell, PRRC