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:	735004079A002Y8
EMDN code	W020201

UDI-DI	Product code	Product name
7350040791172	1420041	Swelab Alfa Plus Basic
7350040791189	1420042	Swelab Alfa Plus Standard
7350040791202	1420044	Swelab Alfa Plus Cap AR
7350040791226	1420046	Swelab Alfa Plus Sampler BD AR

Table 1 – Products included in this Declaration of Conformity

Risk Classification	Class B	According to Rule 6
Intended purpose	The Swelab Alfa Plus is a quantitative, multi-parameter automated hematology analyzer intended for blood cell counting and sizing for in vitro diagnostic use in screening of human capillary or venous whole blood samples collected in K2EDTA or K3EDTA blood collection tubes to collect data reflecting the patient's hematological status. The analyzer must be used together with Swelab Alfa Diluent and Swelab Alfa Lyse. The device is intended for professional use. The Swelab Alfa Plus is used for enumeration of white blood cells (WBC); the absolute number and percentage concentration for granulocytes (GRA), lymphocytes (LYM), mid-sized white cells (MID); red blood cells (RBC); hemoglobin (HGB); mean cell volume of red cells (MCV); hematocrit (HCT); mean cell hemoglobin (MCH); mean cell hemoglobin concentration (MCHC); red cell distribution relative width (RDW%); platelets (PLT); mean platelet volume (MPV). The performance of this device has not been established in pediatric patients under the age of 1 month	
IVDR assessment route	Assessment for CE marking following Annex IX (Chapter I and III), Conformity Assessment Based on a Quality Management System and on Assessment of Technical Documentation	

Applicable European directives and regulations

Regulation/Directive	
EU 2017/746	In Vitro Medical Devices Regulation
2011/65/EU	Restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS) Directive
2006/42/EC	Machinery Directive

Table 2 – Applicable regulations/directives

Notified body	Identification number
BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands	NB 2797

Certificate number	Date of issue
IVDR 745210	2022-11-01

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, 2023-05-23 — Jesper Söderqvist, CEO

Place and date of issue

Spånga, 2023-05-23 — Terese Wasell, PRRC

Place and date of issue