Our ref: SMO 30004783
Date: 2023-08-02

To whom it may concern,
This letter confirms that BSI, an EU Notified Body (EU designation No.2797), has issued EU Quality Management System Certificate No. IVDR 745210 under the In Vitro Diagnostics Regulation (EU) 2017/746 to the medical device manufacturer:

Boule Medical AB
Domnarvsgatan 4,
SE-163 53 Spånga,
Sweden

With the following scope:

Class B Devices	Intended Purpose
IVR 0608 – Devices intended to be used for screening, determination or monitoring of physiological markers.	Quantitative, multi-parameter haematology analysers intended for blood cell counting and sizing in human blood samples.

This Certificate was first issued on 2022-11-01, it is current and valid until 2027-10-31.

BSI performs annual surveillance audits of the manufacturer's quality management system according to the concerned In Vitro Diagnostics Regulation (EU) 2017/746 requirements. The last audit report issued to Manufacturer Name is dated 29th March 2023.

BSI confirms that the products listed in Attachment 1 are covered under IVDR 745210.

The information disclosed under this letter is provided pursuant to express request of Boule Medical AB and is subject to obligations of confidentiality between BSI and Boule Medical AB and of recipient and Boule Medical AB.

BSI confirms that its conditions of contract require Boule Medical AB to notify the Notified Body about incidents and field safety corrective actions.

Yours sincerely,

Karen Leeland

Digitally signed by Karen Leeland
Date: 2023.08.02 11:42:21 +01'00'

Karen Leeland

Scheme Manager

Attachment 1:

IVR 0608 – Devices intended to be used for screening, determination or monitoring of physiological markers.		
Product Name	**Part Number**	**Intended Purpose**
Swelab Alfa Plus Basic	1420041	Quantitative, multi-parameter haematology analysers intended for blood cell counting and sizing in human blood samples.
Swelab Alfa Plus Standard	1420042	
Swelab Alfa Plus Cap AR	1420044	
Swelab Alfa Plus Sampler BD AR	1420046	
Medonic M-series M32B	1420021	
Medonic M-series M32M	1420022	
Medonic M-series M32C AR	1420024	
Medonic M-series M32S BD AR	1420026	