CE	EU DECLARATION OF CONFORMITY (SELF-DECLARATION)	Sterile Safequip® & Chemicals LLP.

Applicable Regulation: In-Vitro Diagnostic Medical Device Regulation (EU) 2017/746, Declaration of Conformity (Annex IV), Self-declaration.

Manufacturer: **Sterile Safequip and Chemicals LLP**
31, Panchratna Industrial Estate, Inside Pirana Gate, S.P. Ring Road, Village Paldi-Kankaj, Daskroi, Ahmedabad -382 425, Gujarat, India.

Declares under sole responsibility that the IVD medical device specified below and to which this declaration relates, conform to the provisions of:

- Regulation (EU) 2017/746 of the European parliament and of the council of 5 April 2017 on In vitro diagnostic medical devices and repealing directive 98/79/EC and Commission decision 2010/227/EU ("IVDR")
- Directive 2011 /65/EU of the European parliament and of the council of 8 June 2011 on the restriction of the use of certain Hazardous Substances in electrical and electronic equipment, including commission delegated directive (EU) 2015/863 of 31 March 2015 amending Annex II to directive 2011 / 65/EU of the European parliament and of the council as regards the list of restricted substances ("ROHS")

Device Information:

The following IVD medical device carries the CE marking and notified in accordance with the IVDR 2017/746.

Generic Name	Erythrocyte Sedimentation Rate (ESR) Analyzer
Brand Name	ZELLESR
Device Type	In-Vitro Diagnostic Medical Device
Model (s)	ZELLESR 10, ZELLESR 20
Technical Specification	**ZELLESR 10 -** Input 110-230V, AC-50-60Hz, Reading Chamber- 10, Display - 4.2" Color touch screen, Loading Capacity - 20 samples per hr, Memory- 9999 sample results.
	ZELLESR 20 - Input 110-230V, AC 50-60Hz, Reading Chamber - 20, Loading Capacity - 40 samples per hr, Display - 4.2" Color touch screen, Memory - 9999 sample result.
Intended Use	An analyzer intended to be used to determine the erythrocyte sedimentation rate (ESR) of red blood cells in an anticoagulated whole blood specimen. It is intended for in-vitro diagnostic use.
Sterilization	Non-sterilized
Material of Construction	Polymer Plastic
Dimension	**Device:** 323mm(L) X 196mm(W)X 187mm(H) **Package:** 425mm(L) X 300mm(W)X 310mm(H)

Risk Classification:

Class A, according to rule 5 of Annex VIII (Products for general laboratory use, Instruments, and specimen receptacles.

Conformity Assessment Route:

Annex II and III technical documentation, Annex IV, Declaration of conformity, Self-declaration.

List of applied (Harmonized) Standards:

	Standard	Description	Tested / Certified by
Safety	IEC 61010-1: 2010	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General Requirements.	**TUV Rhineland**
	IEC 61010-2-081:2015	Safety requirements for electrical equipment for measurement, control, and laboratory use- Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for for analysis and other purposes.	**TUV Rhineland**
	IEC 61010-2-101:2015	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2- 101: Particular requirements for in-vitro diagnostic (IVD) medical equipment.	**TUV Rhineland**
EMC	IEC 61326-1:2020	Electrical equipment for measurement, control, and laboratory use – EMC requirements – Part -1: General requirements.	**TUV Rhineland**
	IEC 61326-2-6: 2020	Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – In vitro diagnostic (IVD) medical equipment.	**TUV Rhineland**
Quality Management System	ISO 13485: 2016	Medical Devices – Quality management systems – Requirements for regulatory requirements.	**BSCIC Certifications Private Limited**

The product has been developed, tested, and verified in accordance with the international standards listed above and this is Declaration of Conformity is issued under the responsibility of the manufacturer.

Start of CE Marking: 19-02-2024

Notified Body: Not Applicable

Authorized Representative: Not Applicable

Revision: Rev 0

Expiry Date: 18-02-2029

The declaration of conformity is solely under the responsibility of the manufacturer.

Ahmedabad, 17-02-2024

Mr. Nilesh Panchal
Person Responsible for Regulatory Compliance (PRCC)

Mr. Kaushal Patel
Managing Director

THIS IS THE CERTIFIED COPY OF THE ORIGINAL DOCUMENT STORED IN ARCHIVE OF SAFEQUIP AND CHEMICALS LLP

Mr. Nilesh Panchal
Person Responsible for Regulatory Compliance (PRRC)