EC DECLARATION OF CONFORMITY

In accordance with 98/79/EEC regulation regarding In-Vitro Medical Diagnostics Devices

DIESSE Diagnostica Senese SpA
with head office in Via A. Solari 19, 20144 Milan, Italy
and plant office in Via delle Rose 10, 53035 Monteriggioni (SI), Italy

certifies

that the design, type of manufacture of the in vitro medical-diagnostic device described hereafter and the version distributed on the market,

conforms

to the

" 98/79/EEC directive relevant to the In Vitro Medical-Diagnostics Devices (IVD)"

CE

through the accomplishment to the Annex III (except section 6) and the essential requirements of Annex I.

This certificate will lose its validity in the event of:
- modifications made to the machine in question without our authorization
- incorrect use of the instrument
- technical interventions performed by unauthorized personnel
- installation of non-original spare parts.

Product:	**Automatic instrument for ESR analysis**
Type:	**MINI-CUBE (code 10392)**
Technical data:	**9V DC; 2A**

conforms

as a whole and in its parts, with the following standards and their amendments:

EN 61010-1	**Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 1: General Requirements. The instrument is classified in Class I.**
EN 61010-2-081	**Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes.**
EN 61010-2-101	**Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment.**
EN 61326-1	**Electrical equipment for measurement, control and laboratory use. EMC requirements. Part 1 - General requirements.**
EN 61326-2-6	**Electrical equipment for measurement, control and laboratory use. EMC requirements. Particular requirements. In vitro diagnostic (IVD) medical equipment.**

And therefore meets the essential requirements of the following Community directives and their amendments:

Low Voltage Directive (2014/35/EU)

Electromagnetic Compatibility Directive (2014/30/EU)

Restriction of Hazardous Substances in Electrical and Electronic Equipment Directive – RoHS2 (2011/65/EU)

Place, date of issue: Monteriggioni, 25 May 2017

Signature:

Grazia Dal Maso
Total Quality Officer

This is the certified copy of the original document stored in archive of DIESSE Diagnostica Senese SpA

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Chiara Muzzi
Head of Regulatory Affairs