

EC DECLARATION OF CONFORMITY

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



DIESSE Diagnostica Senese S.p.A.

with head office in Via A. Solari 19 sc 6, 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-diagnostics 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)”



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 bacteria streaking and incubation unit |
| Type: | ROBOBACT SPECIAL (code 94210) |
| Technical data: | 110/220 Vac (50-60 Hz) |
| Product: | Elaboration and control unit |
| Technical data: | PROCESSING UNIT (code 94224) |
| Type: | 110/220 Vac (50-60 Hz) |

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 ”. |
| EN 61326-1 | “Electrical Equipment for Measurement, Control, and Laboratory Use – Electromagnetic compatibility requirements–Part 1: General requirements” |
| EN 61326-2-6 | “Electrical Equipment for Measurement, Control, and Laboratory Use – Electromagnetic compatibility requirements–Part 2-6: In vitro diagnostic (IVD) medical equipment” |

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

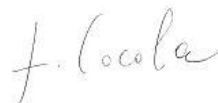
Low Voltage Directive (2006/95/EEC)

Electromagnetic Compatibility Directive (2004/108/EEC)

Place, date of issue:

Monteriggioni, 23 November 2016

Signature:



Francesco Cocola
President

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

Issued: Monteriggioni, 23 November 2016



GRAZIA DAL MASO
TOTAL QUALITY OFFICER