# SEC 02 – DECLARATION OF CONFORMITY

## CHANGE NOTES

| Rev. | Cod. | Change notes |
|---|---|---|
| 00 | MTD_BIOP_TD02DC | First release |
| 01 | | |
| 02 | | |
| 03 | | |
| 04 | | |
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| Prepared by | Verified by | Approved by |
|---|---|---|
| Signature | Signature | Signature |
| Teresa Almonti  | Fausta Brancaccio  | Fausta Brancaccio  |

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Under its own responsibility, the Company

**METEDA Srl**

Legal office: Via Antonio Bosio, 2 – int.10; - 00161 Roma (RM)
Manufacturing site: Via S. Pellico, 4; - 63074 San Benedetto del Tronto (AP)
Via Dell'Olmo, 1; - 63074 San Benedetto del Tronto (AP)

Declares that the Product

*Product*
**Biothesiometer Plus v 1.0**

Code CND: *V030207* Registered on the Italian National Directory under N. *1721530*

meets the essential safety requirements pursuant to Annex I of Legislative Decree 46/97, transposing Medical Device Directive 93/42 EEC, and Annex II of Legislative Decree 37/2010, transposing Directive 2007/47/EEC.

Device Classification: **Class I**, pursuant to regulation 12 of Annex IX

Conformity assessment procedure: Annex II exc. 4 of Medical Device Directive 93/42 EEC

List of applicable updated statutory regulations:

| | |
|---|---|
| UNI EN ISO 9001: 2015 | Quality Manangement system |
| UNI CEI EN ISO 13485: 2016 | Medical Device – Quality management system |
| UNI CEI EN ISO 14971:2012 | Application of risk management to Medical Devices |
| UNI CEI EN ISO 15223-1:2017 | Medical Devices - Symbols to be used with medical device labels, labelling and Information to be supplied - Part 1: General requirements |
| IEC/EN 62304 | Medical Device Software - Software life cycle processes |
| IEC/EN 62366 | Medical Devices - Part 1: Application of usability engineering to medical devices |
| IEC/EN 60601-1:2006 | Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance |
| IEC/EN 60601-1-2:2010 | Medical Electrical Equipment<br>Part 1: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic compatibility - Requirements and tests |

For this purpose, the company guarantees and declares, under its own responsibility:

1. That the list of corresponding product models can be found in Annex 1.
2. That it is committed to maintaining and making available to relevant authorities the Product's technical documentation, for at least ten years from the last release to the market of the last lot or serial number of the devices indicated.
3. That these devices are designed, manufactured, and marketed in accordance with the Product technical documentation, in compliance with EN ISO 13485:2018 Quality Management System standards, as determined by certification body IMQ (CSQ IQNET MED).
4. That METEDA has already taken steps to notify the Italian Ministry of Health of marketing of the aforementioned devices, as well as put in place appropriate post-marketing surveillance measures.

Date
San Benedetto del Tronto, 09.07.2018

Firma / Signature
Legale Rappresentante
Dott.ssa Fausta Brancaccio