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EC DECLARATION OF CONFORMITY

TELIC, SAU declares that the products *ECG ELECTRODES and ACCESORIES* are manufactured according to requirements of the **Medical Devices Directive 93/42/EEC** and meet requirements set in the Essential Requirements of the Annex I of above mentioned Directive.

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|---|--|
| ECG ELECTRODES | Ag/AgCl |
| Commercial brand | DORMO |
| References | LEH-36, LF-50, LF-36, LP-50, LR-50, SX-50, SX-36, SF-36, SX-30, SP-50 |
| CONNECTION ADAPTER | to standard stud |
| Commercial brand | DORMO |
| References | 4013-5, 4013-B |
| Classification | |
| Product class I – Non-sterile. According to Rule 1 of Annex IX of the 93/42/EEC Directive | |
| GMDN | 35035 |
| Standards applied | |
| ANSI/AAMI EC12 Disposable ECG electrodes. 2011/65/EU Directive (RoHS 2) | |

Technical documentation, in accordance with the established in the corresponding annexes of Directive 93/42/EEC, is updated and located in our facilities. We are in position to submit these documents in case of Notified Body or Competent Authority requirement.

Bigues, on 15th May 2015

Xavier Guerrero
Technical Responsible