

Telic, S.A.U.

Polígono Industrial Can Barri C/ Molí d'en Barri, 7-9, 08415 Bigues i Riells, BARCELONA, Spain

Tel: +34 93 865 61 25 Fax: +34 93 865 62 46

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.

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