

EC Declaration of Conformity

We Erenler Medikal Co.,Ltd. herewith declares under its sole responsibility that the item of product specified below satisfies the essential requirements of the EC Medical Devices Directive 93/42/EC with amendment 2007/47/EC directive which are apply to it.

Product Name: Medical Recording/Chart Papers (ECG/CTG papers)

Type-Model: Opmask

GMDN Code: 15639

Classification: Class I, Rule I

Conformity Assesment Route: Annex VII

Applicable EU Directives: 93/43/EEC Medical Devices Devices with amendment 2007/47/EC

Applicable Standards: EN ISO 15223-1:2016, EN 1041:2009, EN ISO 14971:2012, EN ISO 13485:2012

Manufacturer: Erenler Medikal Co., Ltd

Ikitelli O.S. B. Fatih San. Sitesi 3B Blok No: 3/4 34490- Basaksehir Istanbul /Turkey

Tel : +90 212 486 00 37 (140) Fax: +90 212 486 00 38

Country of Origin: Turkey

On Behalf Of Manufacturer:

Name: Ercan Taslicukur

Position: Vice President

Date-Place: Istanbul-Turkey

Signature-Stamp:

**ERENLER MEDİKAL
SAN. TİC. LTD. ŞTİ.**
1. O.S.B. Fatih San. Sitesi 3B Blok No:3-4
Zemin Kat Basaksehir-İSTANBUL
Tel:0212 486 00 37 Fax:0212 486 00 38
İkitelli V.D.:354 015 1052

İKİTELLİ ORG.SAN.BOL.FATİH SANAYİ SİT. 3-B BLOCK NO:3-4 BASAKSEHİR / İSTANBUL

TEL:+90 212 486 00 37 FAX:+90 212 486 00 38

www.erenlermedikal.com info@erenlermedikal.com.tr