



## *EC Declaration of Conformity*

We Beren Medikal Paz. San.Tic.Ltd.Sti. 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 and Thermal Paper for Video Printer

**Type-Model:** Opmask, Opstar

**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 13485:2016, EN 1041:2009, EN ISO 14971:2012, EN ISO 13485:2012

**Certificate No:** MDD1024

**Manufacturer:** Beren Medikal Paz. San.Tic.Ltd.Sti.

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### **On Behalf Of Manufacturer:**

**Name:** Ali Riza Taslicukur

**Position:** General Manager

**Date-Place:** 20/05/2019 Istanbul-Turkey

**Signature-Stamp:**

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