



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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