

DECLARATION OF CONFORMITY

DUZEY MEDİKAL CIHAZLAR SANAYİ TICARET LIMITED SİRKETİ

ADDRESS : İÇMELER MAHALLESİ ÖZYAMAN SOKAK NO:23/A TUZLA/ İSTANBUL- TURKEY
Tel: +90 216 395 55 05 Fax: +90 216 395 35 75 info@duzeymedical.com

General Applicable Directives

Council directive 93/42/EEC of June 1993 concerning Medical Devices(MDD 93/42/EEC)

Product : **SURGICAL POLYPROPYLENE MESH**

Gmdn Code : **60300**

Classification : **Class II b Rule 8**

Applicable Standards:

Production is made in accordance with all applicable standards specified in the document no TF16 in technical file.

Conformity Assessment Procedure:

The conformity assessment has been made, except for Annex II article 4 of the MDD 93 42 EEC directive.

We declare that the above-mentioned product complies with the Medical Devices 93/42/EEC and 2007/47/EC council directives and that the product is produced according to the certified quality assurance system provisions, that we will fulfill the responsibilities brought by this quality system, and that we will maintain this quality system completely and effectively.

We declare that our products do not contain pharmaceuticals, animal tissue, human blood and derivatives, phthalate, latex.

We hereby declare that our quality management system, including the provisions of Annex X for the above-mentioned product, shall be continuously reviewed and corrective and preventive actions shall be applied when necessary and that we shall keep our entire system up to date.

We declare that we have not applied to another notified body for the above-mentioned product.

Signatures

Approved By : **YAKUP KORKMAZ**

Title : **General Manager**



DÜZEY MEDİKAL CIHAZLAR SANAYİ TIC. LTD. ŞTİ.
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Notified Body : **UDEM**
Notified Body No : **2292**
Certificate Number : **M.2016.106.7121**
Issue Date : **11.11.2016**
Initial Lot Numbers : **012105-1**
Expiry Date : **27.05.2024**

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Annex 1 Product List

Surgical Polypropylene Mesh

CODE	PRODUCT	BARCODE NO
DM55	POLYPROPYLENE MESH 5X5 CM	8680081330016
DM510	POLYPROPYLENE MESH 5X10 CM	8680081330023
DM611	POLYPROPYLENE MESH 6X11 CM	8680081330030
DM614	POLYPROPYLENE MESH 6X14 CM	8680081330047
DM7515	POLYPROPYLENE MESH 7.5X15 CM	8680081330054
DM815	POLYPROPYLENE MESH 8X15 CM	8680081330061
DM1015	POLYPROPYLENE MESH 10X15 CM	8680081330078
DM1020	POLYPROPYLENE MESH 10X20 CM	8680081330085
DM1515	POLYPROPYLENE MESH 15X15 CM	8680081330092
DM1520	POLYPROPYLENE MESH 15X20 CM	8680081330108
DM2020	POLYPROPYLENE MESH 20X20 CM	8680081330207
DM1530	POLYPROPYLENE MESH 15X30 CM	8680081330115
DM3040	POLYPROPYLENE MESH 30X40 CM	8680081330122
DM2030	POLYPROPYLENE MESH 20X30 CM	8680081330139
DM3030	POLYPROPYLENE MESH 30X30 CM	8680081330146
DMPS	PLUG MESH Q 7 CM	8680081330153
DMPM	PLUG MESH Q 9 CM	8680081330160
DMPL	PLUG MESH Q 11 CM	8680081330177

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Approved By : YAKUP KORKMAZ

Position : General Manager



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Notified Body : UDEM
Notified Body No : 2292
Certificate Number : M.2016.106.7121
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