



EC DECLARATION CONFORMITY

Member states' laws regulations and administrative documents in relation to construction products with the aim of harmonization of the European Union Council Directive 93/42/EEC-Medical Devices Directives

Name and Adress of the Company	: FONKSİYONEL TEKSTİL LTD. ŞTİ.	
Name and Adress of Production Place	Halil Rifat Paşa Mah. Perpa Tic. Merk. B Blok Kat:12 No:2054 Okmeydanı-İstanbul / TÜRKİYE : FONKSİYONEL TEKSTİL LTD. ŞTİ. Halil Rifat Paşa Mah. Perpa Tic. Merk. B Blok Kat:12 No:2054 Okmeydanı-İstanbul / TÜRKİYE	
Applicable Directive of the assessment	93/42/EEC-Medical Devices Directives	
Category and Postface	The product is subject to Class 1 of the Medical Devices Directive. Annex to Annex, Annex 7 (Declaration of Conformity)	
Product name and types	: Abdominal Pregnancy Corset Varicose Stocking Diabetic Socks	Gmdn : 41031 Gmdn: 30878 Gmdn:30378

We, as the manufacturer, declare that this document and the Re-usable products meet the provisions of Directive 93/42 / EEC applied to them. The medical product has been included in Class 1 according to Annex VII of Directive 93/42 / EEC and carries the CE marking.

Our company manufactures products conforming to the requirements of ISO 13845: 2003 Medical Devices Quality Management System. In addition, it applies TSE EN ISO 14971 (Medical Devices Risk Management) and EN 980: 2003 (Labeling of Medical Devices) Standards.

The products described above have been subjected to initial type tests by the manufacturer and the factory production control has been carried out with regular tests. The required testing and documentation has been provided and certified by the competent authority. The continuity of the tests is provided by the manufacturer.

Issued date: İstanbul - 11/06/2016

Signature
General Manager

Mehtap YETİŞGİN
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