MEDSTER	EC DECLARATION			
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CE

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EC DECLARATION OF CONFORMITY
(EU) No. 2017/745 Regulations of the European Parliament & Council

Company Name	:	Medster Tıbbi Cihaz ve Sağlık Hizmetleri Ltd. Şti.
SRN Code	:	TR-MF-000014781
Auth. Person / Title	:	Aysu ÖZTÜRK / General Manager
Address	:	Başkent Organize Sanayi Bölgesi Malıköy 19. Cad. No: 51 Temelli - Ankara
Phone	:	+90 312 387 05 50
Fax	:	+90 312 387 05 51
Web/Mail	:	info@medster.com.tr

We, hereby declare that our **SafeCheck branded ; Kraft & Tyvek Sterilization Reels, Sterilization Pouches** products listed in **TD.TB.01 Annex-1 Product Model and GMDN code Table** with product names, codes, models and Basic-UDI codes are manufactured according to below harmonized standards and complies with the provisions of the ***(EU) 2017/745 Regulations of the European Parliament & Council (Annex VIII, Rule 1)***
Class I Other (Without Measuring Function, Non-Sterile, Not Reusable

Relevant Harmonized Standards		
EN ISO 13485: 2016	EN ISO 14971: 2019	EN ISO 20417:2021
TS EN 868-5 :2019	TS EN 868-7 :2017	TS EN 868-9 :2019
EN ISO 11140-1:2014	EN ISO 11607-1:2020	EN ISO 11607-2:2020
EN 15223-1: 2021		

Other Regulation, Legislation & Guidelines

(EU) 2017/745 REGULATIONS OF THE EUROPEAN PARLIAMENT & COUNCIL
(Annex VIII, Rule 1)
Class I Other (Without measuring function, non-sterile, not reusable)

This Declaration of conformity is issued only, under responsibility of **Medster Tıbbi Cihaz ve Sağlık Hizmetleri Ltd. Şti.**' Medical device (s) listed in Annex-1, related to Medical devices (EU) MDR 2017/745
We declare that it meets the provision of the regulation. This statement is being supported by quality system approval ISO 13485, given by **IQR International certification services LTD. ŞTI.** All supporting documents stored at Manufacturer's premises.

This declaration is edited according to (EU) No. 2017/745 EUROPEAN PARLIAMENT and COUNCIL STATEMENT Annex IV. EU Declaration of conformity.

First CE Marking Date	:	2018
Declaration Date	:	18.01.2022
Declaration Place	:	Ankara, Türkiye
Declared by	:	Aysu ÖZTÜRK
Signature	:	A. Öztürk