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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](mailto:info@medster.com.tr)

We, hereby declare that our **SafeCheck branded; Bowie Dick Test Packs, Autoclave Tapes & Sterilization Control Strips** products listed in **TD.TB.03 Annex-3 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
EN 15223-1: 2021	EN ISO 11140-1:2014	ISO TR 24971:2020

**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** : 2021  
**Declaration Date** : 18.01.2022  
**Declaration Place** : Ankara, Türkiye  
**Declared by** : Aysu ÖZTÜRK  
**Signature** :