

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

Company Name : Medster Tıbbi Cihaz ve Sağlık Hizmetleri Ltd. Şti.
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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 : 28.03.2023
Declaration Place : Ankara, Türkiye
Declared by : Aysu ÖZTÜRK

Signature

MEDSTER
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Annex-3 Product Models and GMDN Code Table

Document No	Release Date	Revision No	Revision Date
TD.TB.03	09.03.2021	03	28.03.2023

Product Models and GMDN Code Table ;

Medster Safecheck Branded Sterilization Supplies Products

The products are designed to demonstrate the success of sterilization processes. Through the indicators on them, it provides information about the quick loop success.

GMDN 35362- Sterilization process indicator, chemical/physical

EXPLANATION;

A sterilization indicator designed to respond to sterilization processes by means of a characteristic chemical or physical change to one or more of the physical conditions within the sterilizing chamber.

Medster Safecheck Branded Sterilization Supplies Products						
Model Code	UDI-DI	Basic UDI-DI	Model Name	Sizes	GMDN Code	Product Class
10.000	8681227031316	868122703CIWP	Autoclave Tape Without Indicator	19mm x 50m	35362	Class I (Other)
10.010	8681227031798	868122703CIWP	Autoclave Tape Without Indicator	25mm x 50m	35362	Class I (Other)
10.020	8683608037917	868122703CIWP	Autoclave Tape Without Indicator	12mm x 50m	35362	Class I (Other)
10.100	8681227031323	868122703CIWP	Steam Autoclave Tape	19mm x 50m	35362	Class I (Other)
10.110	8681227031736	868122703CIWP	Steam Autoclave Tape	25mm x 50m	35362	Class I (Other)
10.120	8683608037900	868122703CIWP	Steam Autoclave Tape	12mm x 50m	35362	Class I (Other)
10.200	8681227031361	868122703CIWP	EO Autoclave Tape	19mm x 50m	35362	Class I (Other)
10.210	8681227031330	868122703CIWP	EO Autoclave Tape	25mm x 50m	35362	Class I (Other)
10.220	8683608037931	868122703CIWP	EO Autoclave Tape	12mm x 50m	35362	Class I (Other)
10.300	8681227030135	868122703CIWP	Plasma Autoclave Tape	19mm x 50m	35362	Class I (Other)
10.310	8681227031354	868122703CIWP	Plasma Autoclave Tape	25mm x 50m	35362	Class I (Other)
10.320	8683608037924	868122703CIWP	Plasma Autoclave Tape	12mm x 50m	35362	Class I (Other)
20.110	8681227031385	868122703CIWP	Bowie-Dick Test Pack (Wrap Type) 200 sheet	126mm x 128mm x 15mm	35362	Class I (Other)
20.120	8681227031392	868122703CIWP	Bowie-Dick Test Pack (Wrap Type) 400 sheet	126mm x 128mm x 15mm	35362	Class I (Other)
20.210	8681227031378	868122703CIWP	Bowie-Dick Test Pack (Box Type) 200 sheet	13cm x 13cm x 18mm	35362	Class I (Other)
20.220	8681227031415	868122703CIWP	Bowie-Dick Test Pack (Box Type) 400 sheet	130mm x 130mm x 18mm	35362	Class I (Other)
20.250	8681227031927	868122703CIWP	Bowie-Dick Test Pack (Wrap Type) 200 sheet Adhesive	126mm x 128mm x 15mm	35362	Class I (Other)
20.260	8681227032306	868122703CIWP	Bowie-Dick Test Pack (Box Type) 200 sheet Adhesive	130mm x 130cm x 180mm	35362	Class I (Other)
20.290	8681227031934	868122703CIWP	Bowie-Dick Test Pack (Box Type) 400 sheet Adhesive	130mm x 130mm x 18mm	35362	Class I (Other)
20.310	8681227031941	868122703CIWP	Bowie-Dick Test Package (A4 Test Sheet)	114mm x 114mm	35362	Class I (Other)



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20.320	8681227031408	868122703CIWP	Bowie-Dick Test Pack (Wrap Type) 400 sheet Adhesive	126mm x 128mm x 15mm	35362	Class I (Other)
30.100	8681227031439	868122703CIWP	3 line Documentation Label Steam 500s	260mm x 260mm	35362	Class I (Other)
30.101	8681227032337	868122703CIWP	3 line Documentation Label Steam 600s	260mm x 260mm	35362	Class I (Other)
30.120	8681227031958	868122703CIWP	Container Filter	185mm	35362	Class I (Other)
30.200	8681227031514	868122703CIWP	3 line Documentation Label EO 500s	260mm x 260mm	35362	Class I (Other)
30.201	8681227032191	868122703CIWP	3 line Documentation Label EO 600s	260mm x 260mm	35362	Class I (Other)
30.300	8681227031507	868122703CIWP	3 line Documentation Label Plasma 500s	260mm x 260mm	35362	Class I (Other)
30.301	8681227031491	868122703CIWP	3 line Documentation Label Plasma 600s	260mm x 260mm	35362	Class I (Other)
30.400	8681227031446	868122703CIWP	Barcode Label Double Carrier	35mm x 58mm	35362	Class I (Other)
30.410	8681227031453	868122703CIWP	Barcode Label Steam Double Carrier	35mm x 58mm	35362	Class I (Other)
30.420	8681227033389	868122703CIWP	Barcode Label Double Carrier	40mm x 40mm	35362	Class I (Other)
30.500	8681227031750	868122703CIWP	3-Line Label Gun	280mm x 150mm x 60mm	35362	Class I (Other)
30.501	8681227032276	868122703CIWP	3-Line Label Gun (H ₂ O ₂)	280mm x 150mm x 60mm	35362	Class I (Other)
30.600	8681227031460	868122703CIWP	Barcode Label Steam/ETO Double Carrier	40mm x 70mm	35362	Class I (Other)
30.620	8681227031477	868122703CIWP	Barcode Label Single Carrier	35mm x 58mm	35362	Class I (Other)
40.100	8681227031545	868122703CIWP	Chemical Indicator Steam Type 4	68mm x 25mm	35362	Class I (Other)
40.110	8681227031767	868122703CIWP	Chemical Indicator Steam Adhesive Type 4	68mm x 25mm	35362	Class I (Other)
40.200	8681227031552	868122703CIWP	Chemical Indicator Steam Dual Type 4	14mm x 170mm	35362	Class I (Other)
40.210	8681227031774	868122703CIWP	Chemical Indicator Steam Dual Adhesive Type 4	14mm x 170mm	35362	Class I (Other)
40.300	8683608039508	868122703CIWP	Chemical Indicator Formaldehyde Type 4	68mm x 25mm	35362	Class I (Other)
40.400	8681227031484	868122703CIWP	Chemical Indicator-EO Dual Adhesive Type 4	14mm x 170mm	35362	Class I (Other)
50.100	8681227031569	868122703CIWP	Chemical Indicator Steam Type 5	68mm x 25mm	35362	Class I (Other)
50.110	8681227031804	868122703CIWP	Chemical Indicator Steam Adhesive Type 5	68mm x 25mm	35362	Class I (Other)
50.200	8681227031965	868122703CIWP	Chemical Indicator Steam Dual Type 5	14mm x 170mm	35362	Class I (Other)
50.210	8681227031972	868122703CIWP	Chemical Indicator Steam Dual Adhesive Type 5	14mm x 170mm	35362	Class I (Other)
50.500	8681227031576	868122703CIWP	Integrator Chemical Indicator Steam Type 5	22mm x 58mm	35362	Class I (Other)
51.100	8681227031583	868122703CIWP	Chemical Indicator EO Type 5	68mm x 25mm	35362	Class I (Other)
51.110	8681227031828	868122703CIWP	Chemical Indicator EO Adhesive Type 5	68mm x 25mm	35362	Class I (Other)
51.200	8681227031811	868122703CIWP	Chemical Indicator EO Dual Type 5	14mm x 170mm	35362	Class I (Other)
51.210	8681227031835	868122703CIWP	Chemical Indicator EO Dual Adhesive Type 5	14mm x 170mm	35362	Class I (Other)

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60.103	8681227031842	868122703CIWP	Chemical Indicator Steam Type 6 3,5 min	68mm x 25mm	35362	Class I (Other)
60.105	8681227031859	868122703CIWP	Chemical Indicator Steam Type 6 5 min	68mm x 25mm	35362	Class I (Other)
60.107	8681227031590	868122703CIWP	Chemical Indicator Steam Type 6 7 min	68mm x 25mm	35362	Class I (Other)
60.113	8681227031866	868122703CIWP	Chemical Indicator Steam Type 6 3,5 min Adhesive	68mm x 25mm	35362	Class I (Other)
60.115	8681227031873	868122703CIWP	Chemical Indicator Steam Type 6 5 min Adhesive	68mm x 25mm	35362	Class I (Other)
60.117	8681227031880	868122703CIWP	Chemical Indicator Steam Type 6 7 min Adhesive	68mm x 25mm	35362	Class I (Other)
60.180	8683608039836	868122703CIWP	Chemical Indicator Steam Type 6 18 min	68mm x 25mm	35362	Class I (Other)
60.203	8681227031897	868122703CIWP	Chemical Indicator Steam Type 6 3,5 min Dual	14mm x 170mm	35362	Class I (Other)
60.205	8681227031989	868122703CIWP	Chemical Indicator Steam Type 6 5 min Dual	14mm x 170mm	35362	Class I (Other)
60.207	8681227031996	868122703CIWP	Chemical Indicator Steam Type 6 7 min Dual	14mm x 170mm	35362	Class I (Other)
60.213	8681227032009	868122703CIWP	Chemical Indicator Steam Type 6 3,5 min Adhesive Dual	14mm x 170mm	35362	Class I (Other)
60.215	8681227032016	868122703CIWP	Chemical Indicator Steam Type 6 5 min Adhesive Dual	14mm x 170mm	35362	Class I (Other)
60.217	8681227032023	868122703CIWP	Chemical Indicator Steam Type 6 7 min Adhesive Dual	14mm x 170mm	35362	Class I (Other)
60.500	8681227031743	868122703CIWP	Registration Card Type 6 Steam	46mm x 16mm	35362	Class I (Other)
70.100	8681227030142	868122703CIWP	Plasma Indicator Strip (Type 4)	68mm x 25mm	35362	Class I (Other)
70.150	8681227030128	868122703CIWP	Plasma Indicator Strip (Type 5)	68mm x 25mm	35362	Class I (Other)
80.100	8681227031309	868122703CIWP	Container Label - Steam	36mm x 66mm	35362	Class I (Other)
80.200	8681227031286	868122703CIWP	Plastic Security Seal	29mm x 4mm	35362	Class I (Other)
80.210	8681227031903	868122703CIWP	Plastic Security Seal	29mm x 40mm	35362	Class I (Other)
90.100	8681227032030	868122703CIWP	Washing Efficiency Indicator Washing Machine PVC	6,8cm x 2,5cm	35362	Class I (Other)
90.101	8681227031705	868122703CIWP	Washing Machine Apparatus (Holder) PVC	116mm x 4mm	35362	Class I (Other)
90.110	8681227032047	868122703CIWP	Washing Disinfector Cleaning Indicator	30mm x 70mm	35362	Class I (Other)
90.111	8681227032054	868122703CIWP	Washing Disinfector Cleaning Indicator Metal Holder	116mm x 4mm	35362	Class I (Other)
90.112	8681227031712	868122703CIWP	Container Filter	r=94mm	35362	Class I (Other)
90.120	8681227032313	868122703CIWP	Washer Performance Test Indicator	18mm x 53mm x 14mm	35362	Class I (Other)
90.130	8681227031910	868122703CIWP	Washer Performance Test Indicator	-	35362	Class I (Other)
90.131	8681227031729	868122703CIWP	Washer Disinfector Indicator with Lumen	-	35362	Class I (Other)
90.150	8681227032061	868122703CIWP	Ultrasonic Cleaning Indicator	30mm x 70mm	35362	Class I (Other)
90.151	8681227032207	868122703CIWP	Ultrasonic Cleaning Indicator Metal Holder	116mm x 4mm	35362	Class I (Other)
90.160	8681227032078	868122703CIWP	Ultrasonic Bath Cleaning Performance	33mm	35362	Class I



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			Test			(Other)
90.200	8681227032085	868122703CIWP	Helix Test Indicator	152mm x 90mm	35362	Class I (Other)
90.201	8681227032092	868122703CIWP	Helix Test Tool	150cm x 3mm	35362	Class I (Other)
90.210	8683608039829	868122703CIWP	Helix Test Tool Metal	150cm x 16mm	35362	Class I (Other)
90.300	8681227032108	868122703CIWP	Protein Residue Test	50mm x 5mm x 5mm	35362	Class I (Other)

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