



EC DECLARATION OF CONFORMITY

(EU) No. 2017/745 Regulations of the European Parliament & Council

Company Name	: Medster Tıbbi Cihaz ve Saęlık Hizmetleri Ltd. Őti.
SRN Code	: TR-MF-000014781
EMDN Code	: Crepe Sterilization Wrap : S010301 SMS Sterilization Wrap : S010302
Auth. Person / Title	: Aysu ÖZTÜRK / General Manager
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We, hereby declare that our **SafeCheck branded ; SMS and Crepe Sterilization Wrap** products listed in **TD.TB.02 Annex-2 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 868-2 :2017	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 Saęlık Hizmetleri Ltd. Őti.** 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. ŐTI.** 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 : 13.03.2023
Declaration Place : Ankara, Türkiye
Declared by : Aysu ÖZTÜRK

Signature :

MEDSTER
Tıbbi Cihaz ve Sağlık Malzemeleri Ltd. Sti.
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Annex-2 Product Models and GMDN Code Table

Document No	Release Date	Revision No	Revision Date
TD.TB.02	02.07.2018	05	13.03.2023

Product Models and GMDN Code Table ;

Medster Safecheck branded sterilization package (SMS Sheet , Crepe Paper)

Our products are used to provide a sterile barrier property. It is designed to protect the sterile property for the use of the properly packaged medical device.

GMDN 13735: Sterilization packaging, single-use

EXPLANATION;

A device intended to be used to enclose medical devices that are to be sterilized. It is designed to allow sterilization of the enclosed medical device and also to maintain sterility of the device until the packaging is opened for use of the device.

Medster Safecheck Branded Sterilization Package (SMS Sheet, Crepe Paper)

Model Code	UDI-DI	Basic UDI-DI	Model Name	Sizes	Weight	Color	GMDN Code	Product Class
40SMS100100	8681227032672	868122703SCXT	SMS Sheet	100cm x 100cm	40GSM	Blue	13735	Class I (Other)
40SMS120120	8681227032689	868122703SCXT	SMS Sheet	120cm x 120cm	40GSM	Blue	13735	Class I (Other)
40SMS130130	8681227032696	868122703SCXT	SMS Sheet	130cm x 130cm	40GSM	Blue	13735	Class I (Other)
40SMS130150	8681227032702	868122703SCXT	SMS Sheet	130cm x 150cm	40GSM	Blue	13735	Class I (Other)
40SMS140140	8681227032719	868122703SCXT	SMS Sheet	140cm x 140cm	40GSM	Blue	13735	Class I (Other)
40SMS140150	8681227031347	868122703SCXT	SMS Sheet	140cm x 150cm	40GSM	Blue	13735	Class I (Other)
40SMS150150	8681227032726	868122703SCXT	SMS Sheet	150cm x 150cm	40GSM	Blue	13735	Class I (Other)
40SMS160150	8681227032733	868122703SCXT	SMS Sheet	160cm x 150cm	40GSM	Blue	13735	Class I (Other)
40SMS2020	8681227032580	868122703SCXT	SMS Sheet	20cm x 20cm	40GSM	Blue	13735	Class I (Other)
40SMS2525	8681227032597	868122703SCXT	SMS Sheet	25cm x 25cm	40GSM	Blue	13735	Class I (Other)
40SMS3030	8681227032603	868122703SCXT	SMS Sheet	30cm x 30cm	40GSM	Blue	13735	Class I (Other)
40SMS4040	8681227032610	868122703SCXT	SMS Sheet	40cm x 40cm	40GSM	Blue	13735	Class I (Other)
40SMS4545	8681227032627	868122703SCXT	SMS Sheet	45cm x 45cm	40GSM	Blue	13735	Class I (Other)
40SMS5050	8681227032634	868122703SCXT	SMS Sheet	50cm x 50cm	40GSM	Blue	13735	Class I (Other)
40SMS6060	8681227032641	868122703SCXT	SMS Sheet	60cm x 60cm	40GSM	Blue	13735	Class I (Other)
40SMS7575	8681227032658	868122703SCXT	SMS Sheet	75cm x 75cm	40GSM	Blue	13735	Class I (Other)
40SMS9090	8681227032665	868122703SCXT	SMS Sheet	90cm x 90cm	40GSM	Blue	13735	Class I (Other)
45SMS100100	8681227030487	868122703SCXT	SMS Sheet	100cm x 100cm	45GSM	Blue	13735	Class I (Other)
45SMS100150	8681227036670	868122703SCXT	SMS Sheet	100cm x 150cm	45GSM	Blue	13735	Class I (Other)
45SMS100180	8681227036663	868122703SCXT	SMS Sheet	100cm x 180cm	45GSM	Blue	13735	Class I (Other)
45SMS120120	8681227030494	868122703SCXT	SMS Sheet	120cm x 120cm	45GSM	Blue	13735	Class I



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								(Other)
45SMS120150	8681227036694	868122703SCXT	SMS Sheet	120cm x 150cm	45GSM	Blue	13735	Class I (Other)
45SMS120180	8681227036649	868122703SCXT	SMS Sheet	120cm x 180cm	45GSM	Blue	13735	Class I (Other)
45SMS130130	8681227032238	868122703SCXT	SMS Sheet	130cm x 130cm	45GSM	Blue	13735	Class I (Other)
45SMS130150	8681227032566	868122703SCXT	SMS Sheet	130cm x 150cm	45GSM	Blue	13735	Class I (Other)
45SMS135135	8681227036687	868122703SCXT	SMS Sheet	135cm x 135cm	45GSM	Blue	13735	Class I (Other)
45SMS135180	8681227036656	868122703SCXT	SMS Sheet	135cm x 180cm	45GSM	Blue	13735	Class I (Other)
45SMS140140	8681227032245	868122703SCXT	SMS Sheet	140cm x 140cm	45GSM	Blue	13735	Class I (Other)
45SMS150150	8681227030500	868122703SCXT	SMS Sheet	150cm x 150cm	45GSM	Blue	13735	Class I (Other)
45SMS160150	8681227032573	868122703SCXT	SMS Sheet	160cm x 150cm	45GSM	Blue	13735	Class I (Other)
45SMS2020	8681227033372	868122703SCXT	SMS Sheet	20cm x 20cm	45GSM	Blue	13735	Class I (Other)
45SMS2525	8681227030401	868122703SCXT	SMS Sheet	25cm x 25cm	45GSM	Blue	13735	Class I (Other)
45SMS3030	8681227030418	868122703SCXT	SMS Sheet	30cm x 30cm	45GSM	Blue	13735	Class I (Other)
45SMS4040	8681227030425	868122703SCXT	SMS Sheet	40cm x 40cm	45GSM	Blue	13735	Class I (Other)
45SMS4545	8681227030432	868122703SCXT	SMS Sheet	45cm x 45cm	45GSM	Blue	13735	Class I (Other)
45SMS5050	8681227030449	868122703SCXT	SMS Sheet	50cm x 50cm	45GSM	Blue	13735	Class I (Other)
45SMS6060	8681227030456	868122703SCXT	SMS Sheet	60cm x 60cm	45GSM	Blue	13735	Class I (Other)
45SMS7575	8681227030463	868122703SCXT	SMS Sheet	75cm x 75cm	45GSM	Blue	13735	Class I (Other)
45SMS9090	8681227030470	868122703SCXT	SMS Sheet	90cm x 90cm	45GSM	Blue	13735	Class I (Other)
60SMS100100	8681227032832	868122703SCXT	SMS Sheet	100cm x 100cm	60GSM	Blue	13735	Class I (Other)
60SMS120120	8681227032849	868122703SCXT	SMS Sheet	120cm x 120cm	60GSM	Blue	13735	Class I (Other)
60SMS130130	8681227032856	868122703SCXT	SMS Sheet	130cm x 130cm	60GSM	Blue	13735	Class I (Other)
60SMS130150	8681227032863	868122703SCXT	SMS Sheet	130cm x 150cm	60GSM	Blue	13735	Class I (Other)
60SMS140140	8681227032870	868122703SCXT	SMS Sheet	140cm x 140cm	60GSM	Blue	13735	Class I (Other)
60SMS150150	8681227030517	868122703SCXT	SMS Sheet	150cm x 150cm	60GSM	Blue	13735	Class I (Other)
60SMS150180	8683608037894	868122703SCXT	SMS Sheet	150cm x 180cm	60GSM	Blue	13735	Class I (Other)
60SMS160150	8681227032894	868122703SCXT	SMS Sheet	160cm x 150cm	60GSM	Blue	13735	Class I (Other)
60SMS2020	8681227032740	868122703SCXT	SMS Sheet	20cm x 20cm	60GSM	Blue	13735	Class I (Other)
60SMS2525	8681227032757	868122703SCXT	SMS Sheet	25cm x 25cm	60GSM	Blue	13735	Class I (Other)
60SMS3030	8681227032764	868122703SCXT	SMS Sheet	30cm x 30cm	60GSM	Blue	13735	Class I (Other)
60SMS4040	8681227032771	868122703SCXT	SMS Sheet	40cm x 40cm	60GSM	Blue	13735	Class I (Other)



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60SMS4545	8681227032788	868122703SCXT	SMS Sheet	45cm x 45cm	60GSM	Blue	13735	Class I (Other)
60SMS5050	8681227032795	868122703SCXT	SMS Sheet	50cm x 50cm	60GSM	Blue	13735	Class I (Other)
60SMS6060	8681227032801	868122703SCXT	SMS Sheet	60cm x 60cm	60GSM	Blue	13735	Class I (Other)
60SMS7575	8681227032818	868122703SCXT	SMS Sheet	75cm x 75cm	60GSM	Blue	13735	Class I (Other)
60SMS9090	8681227032825	868122703SCXT	SMS Sheet	90cm x 90cm	60GSM	Blue	13735	Class I (Other)
CRB100100	8681227030364	868122703SCXT	Crepe Paper	100cm x 100cm	60GSM	Blue	13735	Class I (Other)
CRB120120	8681227030371	868122703SCXT	Crepe Paper	120cm x 120cm	60GSM	Blue	13735	Class I (Other)
CRB130130	8681227033440	868122703SCXT	Crepe Paper	130cm x 130cm	60GSM	Blue	13735	Class I (Other)
CRB130150	8683608039218	868122703SCXT	Crepe Paper	130cm x 150cm	60GSM	Blue	13735	Class I (Other)
CRB140140	8681227032368	868122703SCXT	Crepe Paper	140cm x 140cm	60GSM	Blue	13735	Class I (Other)
CRB150150	8681227030388	868122703SCXT	Crepe Paper	150cm x 150cm	60GSM	Blue	13735	Class I (Other)
CRB160160	8681227030395	868122703SCXT	Crepe Paper	160cm x 160cm	60GSM	Blue	13735	Class I (Other)
CRB2525	8681227030289	868122703SCXT	Crepe Paper	25cm x 25cm	60GSM	Blue	13735	Class I (Other)
CRB30120	8681227033471	868122703SCXT	Crepe Paper	30cm x 120cm	60GSM	Blue	13735	Class I (Other)
CRB3030	8681227030296	868122703SCXT	Crepe Paper	30cm x 30cm	60GSM	Blue	13735	Class I (Other)
CRB3535	8681227031422	868122703SCXT	Crepe Paper	35cm x 35cm	60GSM	Blue	13735	Class I (Other)
CRB4040	8681227030302	868122703SCXT	Crepe Paper	40cm x 40cm	60GSM	Blue	13735	Class I (Other)
CRB4545	8681227030319	868122703SCXT	Crepe Paper	45cm x 45cm	60GSM	Blue	13735	Class I (Other)
CRB5050	8681227030326	868122703SCXT	Crepe Paper	50cm x 50cm	60GSM	Blue	13735	Class I (Other)
CRB6060	8681227030333	868122703SCXT	Crepe Paper	60cm x 60cm	60GSM	Blue	13735	Class I (Other)
CRB7575	8681227030340	868122703SCXT	Crepe Paper	75cm x 75cm	60GSM	Blue	13735	Class I (Other)
CRB9090	8681227030357	868122703SCXT	Crepe Paper	90cm x 90cm	60GSM	Blue	13735	Class I (Other)
CRG100100	8681227032511	868122703SCXT	Crepe Paper	100cm x 100cm	60GSM	Green	13735	Class I (Other)
CRG120120	8681227032528	868122703SCXT	Crepe Paper	120cm x 120cm	60GSM	Green	13735	Class I (Other)
CRG130130	8681227033457	868122703SCXT	Crepe Paper	130cm x 130cm	60GSM	Green	13735	Class I (Other)
CRG130150	8683608039225	868122703SCXT	Crepe Paper	130cm x 150cm	60GSM	Green	13735	Class I (Other)
CRG140140	8681227032535	868122703SCXT	Crepe Paper	140cm x 140cm	60GSM	Green	13735	Class I (Other)
CRG150150	8681227032542	868122703SCXT	Crepe Paper	150cm x 150cm	60GSM	Green	13735	Class I (Other)
CRG160160	8681227032559	868122703SCXT	Crepe Paper	160cm x 160cm	60GSM	Green	13735	Class I (Other)
CRG2525	8681227032375	868122703SCXT	Crepe Paper	25cm x 25cm	60GSM	Green	13735	Class I (Other)
CRG30120	8681227033488	868122703SCXT	Crepe Paper	30cm x 120cm	60GSM	Green	13735	Class I (Other)

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CRG3030	8681227032382	868122703SCXT	Crepe Paper	30cm x 30cm	60GSM	Green	13735	Class I (Other)
CRG3535	8681227032931	868122703SCXT	Crepe Paper	35cm x 35cm	60GSM	Green	13735	Class I (Other)
CRG4040	8681227032948	868122703SCXT	Crepe Paper	40cm x 40cm	60GSM	Green	13735	Class I (Other)
CRG4545	8681227032467	868122703SCXT	Crepe Paper	45cm x 45cm	60GSM	Green	13735	Class I (Other)
CRG5050	8681227032474	868122703SCXT	Crepe Paper	50cm x 50cm	60GSM	Green	13735	Class I (Other)
CRG6060	8681227032481	868122703SCXT	Crepe Paper	60cm x 60cm	60GSM	Green	13735	Class I (Other)
CRG7575	8681227032498	868122703SCXT	Crepe Paper	75cm x 75cm	60GSM	Green	13735	Class I (Other)
CRG9090	8681227032504	868122703SCXT	Crepe Paper	90cm x 90cm	60GSM	Green	13735	Class I (Other)
CRI100100	8683608039041	868122703SCXT	Crepe Paper	100cm x 100cm	60GSM	Blue-Green	13735	Class I (Other)
CRI120120	8683608039058	868122703SCXT	Crepe Paper	120cm x 120cm	60GSM	Blue-Green	13735	Class I (Other)
CRI130130	8683608039065	868122703SCXT	Crepe Paper	130cm x 130cm	60GSM	Blue-Green	13735	Class I (Other)
CRI130150	8683608039249	868122703SCXT	Crepe Paper	130cm x 150cm	60GSM	Blue-Green	13735	Class I (Other)
CRI140140	8683608039072	868122703SCXT	Crepe Paper	140cm x 140cm	60GSM	Blue-Green	13735	Class I (Other)
CRI150150	8683608039089	868122703SCXT	Crepe Paper	150cm x 150cm	60GSM	Blue-Green	13735	Class I (Other)
CRI160160	8683608038938	868122703SCXT	Crepe Paper	160cm x 160cm	60GSM	Blue-Green	13735	Class I (Other)
CRI2525	8683608038945	868122703SCXT	Crepe Paper	25cm x 25cm	60GSM	Blue-Green	13735	Class I (Other)
CRI30120	8683608038969	868122703SCXT	Crepe Paper	30cm x 120cm	60GSM	Blue-Green	13735	Class I (Other)
CRI3030	8683608038952	868122703SCXT	Crepe Paper	30cm x 30cm	60GSM	Blue-Green	13735	Class I (Other)
CRI3535	8683608038976	868122703SCXT	Crepe Paper	35cm x 35cm	60GSM	Blue-Green	13735	Class I (Other)
CRI4040	8683608038983	868122703SCXT	Crepe Paper	40cm x 40cm	60GSM	Blue-Green	13735	Class I (Other)
CRI4545	8683608038990	868122703SCXT	Crepe Paper	45cm x 45cm	60GSM	Blue-Green	13735	Class I (Other)
CRI5050	8683608038839	868122703SCXT	Crepe Paper	50cm x 50cm	60GSM	Blue-Green	13735	Class I (Other)
CRI6060	8683608038846	868122703SCXT	Crepe Paper	60cm x 60cm	60GSM	Blue-Green	13735	Class I (Other)
CRI7575	8683608038853	868122703SCXT	Crepe Paper	75cm x 75cm	60GSM	Blue-Green	13735	Class I (Other)
CRI9090	8683608039096	868122703SCXT	Crepe Paper	90cm x 90cm	60GSM	Blue-Green	13735	Class I (Other)
CRW100100	8681227033044	868122703SCXT	Crepe Paper	100cm x 100cm	60GSM	White	13735	Class I (Other)
CRW120120	8681227033051	868122703SCXT	Crepe Paper	120cm x 120cm	60GSM	White	13735	Class I (Other)
CRW130130	8681227033464	868122703SCXT	Crepe Paper	130cm x 130cm	60GSM	White	13735	Class I (Other)
CRW140140	8681227033068	868122703SCXT	Crepe Paper	140cm x 140cm	60GSM	White	13735	Class I (Other)
CRW150150	8681227033075	868122703SCXT	Crepe Paper	150cm x 150cm	60GSM	White	13735	Class I (Other)
CRW160160	8681227033082	868122703SCXT	Crepe Paper	160cm x 160cm	60GSM	White	13735	Class I (Other)

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CRW2525	8681227032955	868122703SCXT	Crepe Paper	25cm x 25cm	60GSM	White	13735	Class I (Other)
CRW30120	8681227033495	868122703SCXT	Crepe Paper	30cm x 120cm	60GSM	White	13735	Class I (Other)
CRW3030	8681227032962	868122703SCXT	Crepe Paper	30cm x 30cm	60GSM	White	13735	Class I (Other)
CRW3535	8681227032979	868122703SCXT	Crepe Paper	35cm x 35cm	60GSM	White	13735	Class I (Other)
CRW4040	8681227032986	868122703SCXT	Crepe Paper	40cm x 40cm	60GSM	White	13735	Class I (Other)
CRW4545	8681227032993	868122703SCXT	Crepe Paper	45cm x 45cm	60GSM	White	13735	Class I (Other)
CRW5050	8681227033006	868122703SCXT	Crepe Paper	50cm x 50cm	60GSM	White	13735	Class I (Other)
CRW6060	8681227033013	868122703SCXT	Crepe Paper	60cm x 60cm	60GSM	White	13735	Class I (Other)
CRW7575	8681227033020	868122703SCXT	Crepe Paper	75cm x 75cm	60GSM	White	13735	Class I (Other)
CRW9090	8681227033037	868122703SCXT	Crepe Paper	90cm x 90cm	60GSM	White	13735	Class I (Other)

Prepared by
Management Representative
Fatma PEKCAN



Confirmed by
General Manager
Aysu ÖZTÜRK

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