

**ES PROHLÁŠENÍ O SHODĚ**
(EU) č. 2017/745 Nařízení evropského parlamentu a rady

Název společnosti : Medster Tibbi Cihaz ve Sağlık Hizmetleri Ltd. Şti.
SRN kód : **Not received yet.**
Autorizační osoba : Aysu ÖZTÜRK / General Manager
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Výrobky uvedené v následující tabulce obsahují názvy, kódy a základní UDI kódy, **TD.TB.02 Příloha 2 - modifikaci výrobku, GMDN kódy, kódy bezpečnostní kontroly; SMS obaly a obaly z krepového papíru**

Odpovídající harmonizované normy

EN ISO 13485: 2016	EN ISO 14971: 2019	EN 1041: 2008
TS EN 868-2 :2017	EN ISO 11607-1:2020	EN ISO 11607-2:2020
EN 15223-1: 2016		

Další Nařízení, legislativa a standardy

NAŘÍZENÍ EVROPSKÉHO PARLAMENTU
A RADY 2017/745

Prohlašujeme, že výrobky vyrobené podle harmonizovaných norem a

(AB) NAŘÍZENÍ EVROPSKÉHO PARLAMENTU A RADY 2017/745

(příloha VIII, Pravidlo 1)

Třída rizika I Ostatní (bez měřicí funkce, nesterilní, bez opakovaného použití

vyhovují ustanovením.

Toto prohlášení o shodě je vystaveno na výhradní zodpovědnost **Medster Tibbi Cihaz ve Sağlık Hizmetleri Ltd. Sti** Zdravotnický prostředek (prostředky) uvedené v Příloze -1, vztahující se k Nařízení evropského parlamentu a rady MDR 2017/745

Prohlašujeme, že splňuje požadavky tohoto nařízení. Prohlášení je založeno na schváleném Systému kvality ISO 13485, vydaném IQR.

Toto prohlášení je upraveno na základě (EU) Nařízení evropského parlamentu a rady č. 2017/745, příloha IV. ES Prohlášení o shodě.

Datum prvního označení CE : 2018
Datum vystavení Prohlášení : 10.06.2021
Místo vystavení Prohlášení : Ankara, Túrkiye
Vystaveno kým : Aysu ÖZTÜRK

Podpis :

MEDSTER
Tibbi Cihaz ve Saęlık Hizmetleri Ltd. Őti.
Malıköy Bařkent OSB Mah. 19. Cad. No:51 Sincan/Ankara
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SINCAN VD 613 085 7804

Product Models and GMDN Code Table ;**Medster Safecheck branded sterilization package (SMS Wrap , Crape 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 Wrap , Crape Paper)

Model Code	Barcode	Basic UDI Code	Model Name	Sizes	Weight	Color	GMDN Kodu	Product Class
40SMS100100	8681227032672	86812270326726G	SMS Wrap	100cm x 100cm	40GSM	Blue	13735	Class I (Other)
40SMS120120	8681227032689	86812270326896Z	SMS Wrap	120cm x 120cm	40GSM	Blue	13735	Class I (Other)
40SMS130130	8681227032696	86812270326966W	SMS Wrap	130cm x 130cm	40GSM	Blue	13735	Class I (Other)
40SMS130150	8681227032702	86812270327025Y	SMS Wrap	130cm x 150cm	40GSM	Blue	13735	Class I (Other)
40SMS140140	8681227032719	86812270327196H	SMS Wrap	140cm x 140cm	40GSM	Blue	13735	Class I (Other)
40SMS140150	8681227031347	86812270313475T	SMS Wrap	140cm x 150cm	40GSM	Blue	13735	Class I (Other)
40SMS150150	8681227032726	86812270327266E	SMS Wrap	150cm x 150cm	40GSM	Blue	13735	Class I (Other)
40SMS160150	8681227032733	86812270327336B	SMS Wrap	160cm x 150cm	40GSM	Blue	13735	Class I (Other)
40SMS2020	8681227032580	86812270325806A	SMS Wrap	20cm x 20cm	40GSM	Blue	13735	Class I (Other)
40SMS2525	8681227032597	86812270325976T	SMS Wrap	25cm x 25cm	40GSM	Blue	13735	Class I (Other)
40SMS3030	8681227032603	86812270326035V	SMS Wrap	30cm x 30cm	40GSM	Blue	13735	Class I (Other)
40SMS4040	8681227032610	86812270326105S	SMS Wrap	40cm x 40cm	40GSM	Blue	13735	Class I (Other)
40SMS4545	8681227032627	86812270326276B	SMS Wrap	45cm x 45cm	40GSM	Blue	13735	Class I (Other)
40SMS5050	8681227032634	868122703263468	SMS Wrap	50cm x 50cm	40GSM	Blue	13735	Class I (Other)
40SMS6060	8681227032641	868122703264165	SMS Wrap	60cm x 60cm	40GSM	Blue	13735	Class I (Other)
40SMS7575	8681227032658	86812270326586N	SMS Wrap	75cm x 75cm	40GSM	Blue	13735	Class I (Other)
40SMS9090	8681227032665	86812270326656K	SMS Wrap	90cm x 90cm	40GSM	Blue	13735	Class I (Other)
45SMS100100	8681227030487	868122703048765	SMS Wrap	100cm x 100cm	45GSM	Blue	13735	Class I (Other)
45SMS120120	8681227030494	868122703049462	SMS Wrap	120cm x 120cm	45GSM	Blue	13735	Class I

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Annex-2 Product Models and GMDN Code Table

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								(Other)
45SMS130130	8681227032238	86812270322385U	SMS Wrap	130cm x 130cm	45GSM	Blue	13735	Class I (Other)
45SMS130150	8681227032566	86812270325666G	SMS Wrap	130cm x 150cm	45GSM	Blue	13735	Class I (Other)
45SMS140140	8681227032245	86812270322455R	SMS Wrap	140cm x 140cm	45GSM	Blue	13735	Class I (Other)
45SMS150150	8681227030500	868122703050054	SMS Wrap	150cm x 150cm	45GSM	Blue	13735	Class I (Other)
45SMS160150	8681227032573	86812270325736D	SMS Wrap	160cm x 150cm	45GSM	Blue	13735	Class I (Other)
45SMS2020	8681227033372	868122703337268	SMS Wrap	20cm x 20cm	45GSM	Blue	13735	Class I (Other)
45SMS2525	8681227030401	86812270304014Z	SMS Wrap	25cm x 25cm	45GSM	Blue	13735	Class I (Other)
45SMS3030	8681227030418	86812270304185J	SMS Wrap	30cm x 30cm	45GSM	Blue	13735	Class I (Other)
45SMS4040	8681227030425	86812270304255F	SMS Wrap	40cm x 40cm	45GSM	Blue	13735	Class I (Other)
45SMS4545	8681227030432	86812270304325C	SMS Wrap	45cm x 45cm	45GSM	Blue	13735	Class I (Other)
45SMS5050	8681227030449	86812270304495V	SMS Wrap	50cm x 50cm	45GSM	Blue	13735	Class I (Other)
45SMS6060	8681227030456	86812270304565S	SMS Wrap	60cm x 60cm	45GSM	Blue	13735	Class I (Other)
45SMS7575	8681227030463	86812270304635P	SMS Wrap	75cm x 75cm	45GSM	Blue	13735	Class I (Other)
45SMS9090	8681227030470	86812270304705L	SMS Wrap	90cm x 90cm	45GSM	Blue	13735	Class I (Other)
60SMS100100	8681227032832	86812270328326E	SMS Wrap	100cm x 100cm	60GSM	Blue	13735	Class I (Other)
60SMS120120	8681227032849	86812270328496X	SMS Wrap	120cm x 120cm	60GSM	Blue	13735	Class I (Other)
60SMS130130	8681227032856	86812270328566U	SMS Wrap	130cm x 130cm	60GSM	Blue	13735	Class I (Other)
60SMS130150	8681227032863	86812270328636R	SMS Wrap	130cm x 150cm	60GSM	Blue	13735	Class I (Other)
60SMS140140	8681227032870	86812270328706N	SMS Wrap	140cm x 140cm	60GSM	Blue	13735	Class I (Other)
60SMS150150	8681227030517	86812270305175M	SMS Wrap	150cm x 150cm	60GSM	Blue	13735	Class I (Other)
60SMS160150	8681227032894	868122703289474	SMS Wrap	160cm x 150cm	60GSM	Blue	13735	Class I (Other)
60SMS2020	8681227032740	868122703274068	SMS Wrap	20cm x 20cm	60GSM	Blue	13735	Class I (Other)
60SMS2525	8681227032757	86812270327576R	SMS Wrap	25cm x 25cm	60GSM	Blue	13735	Class I (Other)
60SMS3030	8681227032764	86812270327646N	SMS Wrap	30cm x 30cm	60GSM	Blue	13735	Class I (Other)
60SMS4040	8681227032771	86812270327716K	SMS Wrap	40cm x 40cm	60GSM	Blue	13735	Class I (Other)
60SMS4545	8681227032788	868122703278874	SMS Wrap	45cm x 45cm	60GSM	Blue	13735	Class I (Other)
60SMS5050	8681227032795	86812270327956Z	SMS Wrap	50cm x 50cm	60GSM	Blue	13735	Class I (Other)

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60SMS6060	8681227032801	868122703280163	SMS Wrap	60cm x 60cm	60GSM	Blue	13735	Class I (Other)
60SMS7575	8681227032818	86812270328186L	SMS Wrap	75cm x 75cm	60GSM	Blue	13735	Class I (Other)
60SMS9090	8681227032825	86812270328256H	SMS Wrap	90cm x 90cm	60GSM	Blue	13735	Class I (Other)
CRB140140	8681227032368	86812270323686A	Crape Paper	140cm x 140cm	60GSM	Blue	13735	Class I (Other)
CRB100100	8681227030364	86812270303645L	Crape Paper	100cm x 100cm	60GSM	Blue	13735	Class I (Other)
CRB120120	8681227030371	86812270303715H	Crape Paper	120cm x 120cm	60GSM	Blue	13735	Class I (Other)
CRB130130	8681227033440	86812270334405Y	Crape Paper	130cm x 130cm	60GSM	Blue	13735	Class I (Other)
CRB150150	8681227030388	868122703038862	Crape Paper	150cm x 150cm	60GSM	Blue	13735	Class I (Other)
CRB160160	8681227030395	86812270303955X	Crape Paper	160cm x 160cm	60GSM	Blue	13735	Class I (Other)
CRB2525	8681227030289	86812270302895X	Crape Paper	25cm x 25cm	60GSM	Blue	13735	Class I (Other)
CRB3030	8681227030296	86812270302965U	Crape Paper	30cm x 30cm	60GSM	Blue	13735	Class I (Other)
CRB30120	8681227033471	86812270334716B	Crape Paper	30cm x 120cm	60GSM	Blue	13735	Class I (Other)
CRB3535	8681227031422	86812270314225G	Crape Paper	35cm x 35cm	60GSM	Blue	13735	Class I (Other)
CRB4040	8681227030302	86812270303024W	Crape Paper	40cm x 40cm	60GSM	Blue	13735	Class I (Other)
CRB4545	8681227030319	86812270303195F	Crape Paper	45cm x 45cm	60GSM	Blue	13735	Class I (Other)
CRB5050	8681227030326	86812270303265C	Crape Paper	50cm x 50cm	60GSM	Blue	13735	Class I (Other)
CRB6060	8681227030333	868122703033359	Crape Paper	60cm x 60cm	60GSM	Blue	13735	Class I (Other)
CRB7575	8681227030340	868122703034056	Crape Paper	75cm x 75cm	60GSM	Blue	13735	Class I (Other)
CRB9090	8681227030357	86812270303575P	Crape Paper	90cm x 90cm	60GSM	Blue	13735	Class I (Other)
CRG100100	8681227032511	86812270325115P	Crape Paper	100cm x 100cm	60GSM	Blue	13735	Class I (Other)
CRG120120	8681227032528	868122703252868	Crape Paper	120cm x 120cm	60GSM	Green	13735	Class I (Other)
CRG130130	8681227033457	86812270334576H	Crape Paper	130cm x 130cm	60GSM	Green	13735	Class I (Other)
CRG140140	8681227032535	868122703253565	Crape Paper	140cm x 140cm	60GSM	Green	13735	Class I (Other)
CRG150150	8681227032542	868122703254262	Crape Paper	150cm x 150cm	60GSM	Green	13735	Class I (Other)
CRG160160	8681227032559	86812270325596K	Crape Paper	160cm x 160cm	60GSM	Green	13735	Class I (Other)
CRG2525	8681227032375	868122703237567	Crape Paper	25cm x 25cm	60GSM	Green	13735	Class I (Other)
CRG3030	8681227032382	868122703238264	Crape Paper	30cm x 30cm	60GSM	Green	13735	Class I (Other)
CRG30120	8681227033488	86812270334886U	Crape Paper	30cm x 120cm	60GSM	Green	13735	Class I (Other)

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TD.TB.02	02.07.2018	01	26.01.2020

CRG3535	8681227032931	86812270329316H	Crape Paper	35cm x 35cm	60GSM	Green	13735	Class I (Other)
CRG4040	8681227032948	868122703294872	Crape Paper	40cm x 40cm	60GSM	Green	13735	Class I (Other)
CRG4545	8681227032467	86812270324676D	Crape Paper	45cm x 45cm	60GSM	Green	13735	Class I (Other)
CRG5050	8681227032474	86812270324746A	Crape Paper	50cm x 50cm	60GSM	Green	13735	Class I (Other)
CRG6060	8681227032481	868122703248167	Crape Paper	60cm x 60cm	60GSM	Green	13735	Class I (Other)
CRG7575	8681227032498	86812270324986Q	Crape Paper	75cm x 75cm	60GSM	Green	13735	Class I (Other)
CRG9090	8681227032504	86812270325045S	Crape Paper	90cm x 90cm	60GSM	Green	13735	Class I (Other)
CRW100100	8681227033044	86812270330445L	Crape Paper	100cm x 100cm	60GSM	Green	13735	Class I (Other)
CRW120120	8681227033051	86812270330515H	Crape Paper	120cm x 120cm	60GSM	White	13735	Class I (Other)
CRW130130	8681227033464	86812270334646E	Crape Paper	130cm x 130cm	60GSM	White	13735	Class I (Other)
CRW140140	8681227033068	868122703306862	Crape Paper	140cm x 140cm	60GSM	White	13735	Class I (Other)
CRW150150	8681227033075	86812270330755X	Crape Paper	150cm x 150cm	60GSM	White	13735	Class I (Other)
CRW160160	8681227033082	86812270330825U	Crape Paper	160cm x 160cm	60GSM	White	13735	Class I (Other)
CRW2525	8681227032955	86812270329556X	Crape Paper	25cm x 25cm	60GSM	White	13735	Class I (Other)
CRW3030	8681227032962	86812270329626U	Crape Paper	30cm x 30cm	60GSM	White	13735	Class I (Other)
CRW30120	8681227033495	86812270334956R	Crape Paper	30cm x 120cm	60GSM	White	13735	Class I (Other)
CRW3535	8681227032979	86812270329797D	Crape Paper	35cm x 35cm	60GSM	White	13735	Class I (Other)
CRW4040	8681227032986	86812270329867A	Crape Paper	40cm x 40cm	60GSM	White	13735	Class I (Other)
CRW4545	8681227032993	868122703299377	Crape Paper	45cm x 45cm	60GSM	White	13735	Class I (Other)
CRW5050	8681227033006	86812270330065C	Crape Paper	50cm x 50cm	60GSM	White	13735	Class I (Other)
CRW6060	8681227033013	868122703301359	Crape Paper	60cm x 60cm	60GSM	White	13735	Class I (Other)
CRW7575	8681227033020	868122703302056	Crape Paper	75cm x 75cm	60GSM	White	13735	Class I (Other)
CRW9090	8681227033037	86812270330375P	Crape Paper	90cm x 90cm	60GSM	White	13735	Class I (Other)

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