

DECLARATION OF CONFORMITY



**PLASTİ-MED PLASTİK MEDİKAL ÜRÜNLER SANAYİ VE
TİCARET LİMİTED ŞİRKETİ**

MANUFACTURER ADRESS : Plasti-med Plastik Medikal Ürünler Sanayi ve Ticaret Limited Şirketi
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Product : CLOSED WOUND DRAINAGE SYSTEMS AND ACCESSORIES

Classification : Class II A, Rule 7 according to MDD 93/42/EEC (2007/47/EC) Annex IX

NOTIFIED BODY : Kiwa Certification Services Inc.

İTOSB 9. Cadde No:15 Tepeören Tuzla İstanbul TÜRKİYE

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NOTIFIED BODY NO : 1984

CERTIFICATION NUMBER : 1984-MDD-11-100

CERTIFICATION ROUTE : ANNEX 2 FULL QUALITY MANAGEMENT SYSTEM (EXCEPT FOR SECTION 4)

We declare that the products as per attached schedule in our delivered version complies with the appropriate basic safety and health requirements of the Medical Device Directive 93/42/EEC (2007/47/EC) based on its design and type, as brought into circulation by us. In case of alteration of the machine, not agreed upon by us, this declaration will lose its validity.

General Applicable Directives

Medical device Directive 93/42/EEC (2007/47/EC)

RELEVANT STANDARDS

TS EN ISO 14971:2012 Medical devices - Application of risk management to medical device

TS EN ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

TS EN 1041+A1:2014 Information supplied by the manufacturer of medical devices.

TS EN ISO 11135-1:2014 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices.

TS EN ISO 20697:2018 Sterile Drainage Catheters and accessory devices for single use

TS EN 1618:2000 Catheters other than intravascular catheters test methods for common properties

Issue Date : 09.11.2009

Signature :

Name : Muammer BERKSÖZ

Position : General Manager

Product Schedule:

REF NO	PRODUCT NAME	GMDN CODE	REF NO	PRODUCT NAME	GMDN CODE
101010	SOFT DRAIN 10 CH/ 100 CM WITH DRAINAGE BAG	35824	103821	SOFT DRAIN 21 CH WITH DRAINAGE BAG- SILICONE	35824
101012	SOFT DRAIN 12 CH/ 100 CM WITH DRAINAGE BAG	35824	103822	SOFT DRAIN 22 CH WITH DRAINAGE BAG- SILICONE	35824
101014	SOFT DRAIN 14 CH/ 100 CM WITH DRAINAGE BAG	35824	103824	SOFT DRAIN 24 CH WITH DRAINAGE BAG- SILICONE	35824
101015	SOFT DRAIN 15 CH/ 100 CM WITH DRAINAGE BAG	35824	103826	SOFT DRAIN 26 CH WITH DRAINAGE BAG- SILICONE	35824
101016	SOFT DRAIN 16 CH/ 100 CM WITH DRAINAGE BAG	35824	103827	SOFT DRAIN 27 CH WITH DRAINAGE BAG- SILICONE	35824
101018	SOFT DRAIN 18 CH/ 100 CM WITH DRAINAGE BAG	35824	103828	SOFT DRAIN 28 CH WITH DRAINAGE BAG- SILICONE	35824
101020	SOFT DRAIN 20 CH/ 100 CM WITH DRAINAGE BAG	35824	103830	SOFT DRAIN 30 CH WITH DRAINAGE BAG- SILICONE	35824
101021	SOFT DRAIN 21 CH/ 100 CM WITH DRAINAGE BAG	35824	103705	FLAT DRAIN 2*5 mm	11305
101022	SOFT DRAIN 22 CH/ 100 CM WITH DRAINAGE BAG	35824	103707	FLAT DRAIN 3*7 mm	11305
101024	SOFT DRAIN 24 CH/ 100 CM WITH DRAINAGE BAG	35824	103710	FLAT DRAIN 4*10 mm	11305
101026	SOFT DRAIN 26 CH/ 100 CM WITH DRAINAGE BAG	35824	103712	ROUND SILICONE DRAIN 12 CH	11305
101027	SOFT DRAIN 27 CH/ 100 CM WITH DRAINAGE BAG	35824	103713	FLAT DRAIN 13 mm	11305
101028	SOFT DRAIN 28 CH/ 100 CM WITH DRAINAGE BAG	35824	103715	ROUND SILICONE DRAIN 15 CH	11305
101030	SOFT DRAIN 30 CH/ 100 CM WITH DRAINAGE BAG	35824	103718	ROUND SILICONE DRAIN 18 CH	11305
103812	SOFT DRAIN 12 CH WITH DRAINAGE BAG - SILICONE	35824	103721	ROUND SILICONE DRAIN 21 CH	11305
103814	SOFT DRAIN 14 CH WITH DRAINAGE BAG - SILICONE	35824	103722	ROUND SILICONE DRAIN 22 CH	11305
103815	SOFT DRAIN 15 CH WITH DRAINAGE BAG - SILICONE	35824	103724	ROUND SILICONE DRAIN 24 CH	11305
103816	SOFT DRAIN 16 CH WITH DRAINAGE BAG - SILICONE	35824	103727	ROUND SILICONE DRAIN 27 CH	11305
103818	SOFT DRAIN 18 CH WITH DRAINAGE BAG- SILICONE	35824	103730	ROUND SILICONE DRAIN 30 CH	11305
103820	SOFT DRAIN 20 CH WITH DRAINAGE BAG- SILICONE	35824			
103008	WOUND DRAINAGE SET 400 cc SINGLE TROCAR 08CH	35824	103406	WOUND DRAINAGE SET MINI 06CH	35824
103010	WOUND DRAINAGE SET 400 CC SINGLE TROCAR 10CH	35824	103407	WOUND DRAINAGE SET MINI 07CH	35824
103012	WOUND DRAINAGE SET 400 cc SINGLE TROCAR 12CH	35824	103408	WOUND DRAINAGE SET MINI 08CH	35824
103014	WOUND DRAINAGE SET 400 CC SINGLE TROCAR 14CH	35824	103410	WOUND DRAINAGE SET MINI 10CH	35824
103016	WOUND DRAINAGE SET 400 CC SINGLE TROCAR 16CH	35824	103507	WOUND DRAINAGE SET SILICONE 200cc-FLAT DRAIN 7 mm	35824
103018	WOUND DRAINAGE SET 400 cc SINGLE TROCAR 18CH	35824	103510	WOUND DRAINAGE SET SILICONE 200cc-FLAT DRAIN 10 mm	35824
103108	WOUND DRAINAGE SET 400 cc DOUBLE TROCAR 08CH	35824	103513	WOUND DRAINAGE SET SILICONE 200cc-FLAT DRAIN 13 mm	35824
103110	WOUND DRAINAGE SET 400 CC DOUBLE TROCAR 10CH	35824	103607	WOUND DRAINAGE SET PVC 400cc-FLAT DRAIN 7 mm	35824
103112	WOUND DRAINAGE SET 400 cc DOUBLE TROCAR 12CH	35824	103610	WOUND DRAINAGE SET PVC 400cc-FLAT DRAIN 10 mm	35824
103114	WOUND DRAINAGE SET 400 CC DOUBLE TROCAR 14CH	35824	103613	WOUND DRAINAGE SET PVC 400cc-FLAT DRAIN 13 mm	35824
103116	WOUND DRAINAGE SET 400 CC DOUBLE TROCAR 16CH	35824	103657	WOUND DRAINAGE SET PVC 200cc-FLAT DRAIN 7 mm	35824
103118	WOUND DRAINAGE SET 400 cc DOUBLE TROCAR 18CH	35824	103660	WOUND DRAINAGE SET PVC 200cc-FLAT DRAIN 10 mm	35824
103208	WOUND DRAINAGE SET 200 cc SINGLE TROCAR 08CH	35824	103673	WOUND DRAINAGE SET PVC 200cc-FLAT DRAIN 13 mm	35824
103210	WOUND DRAINAGE SET 200 CC SINGLE TROCAR 10CH	35824	103517	WOUND DRAINAGE SET SILICONE 100cc-FLAT DRAIN 7 mm	35824
103212	WOUND DRAINAGE SET 200 cc SINGLE TROCAR 12CH	35824	103520	WOUND DRAINAGE SET SILICONE 100cc-FLAT DRAIN 10 mm	35824
103214	WOUND DRAINAGE SET 200 CC SINGLE TROCAR 14CH	35824	103523	WOUND DRAINAGE SET SILICONE 100cc-FLAT DRAIN 13 mm	35824
103216	WOUND DRAINAGE SET 200 CC SINGLE TROCAR 16CH	35824	103527	WOUND DRAINAGE SET SILICONE 400cc-FLAT DRAIN 7 mm	35824
103218	WOUND DRAINAGE SET 200 cc SINGLE TROCAR 18CH	35824	103530	WOUND DRAINAGE SET SILICONE 400cc-FLAT DRAIN 10 mm	35824
103308	WOUND DRAINAGE SET 200 cc DOUBLE TROCAR 08CH	35824	103533	WOUND DRAINAGE SET SILICONE 400cc-FLAT DRAIN 13 mm	35824
103310	WOUND DRAINAGE SET 200 CC DOUBLE TROCAR 10CH	35824	103312	WOUND DRAINAGE SET 200 cc DOUBLE TROCAR 12CH	35824
103314	WOUND DRAINAGE SET 200 CC DOUBLE TROCAR 14CH	35824	103316	WOUND DRAINAGE SET 200 CC DOUBLE TROCAR 16CH	35824
103318	WOUND DRAINAGE SET 200 cc DOUBLE TROCAR 18CH	35824			