



DECLARATION OF CONFORMITY

According to the EU legislation 2017/745

We,

MANUFACTURER

Ammad Surgical
41-B Commercial Area, Cavalry Ground,
Cantt. Lahore – Pakistan. 54000
Tel: +92 (0)42 36610070
Email: info@ammadsurgical.com
SRN # PK-MF-000009603

AUTHORIZED REPRESENTATIVE

Obelis S.A.
Bd General Wahis, 53,
B-1030 Brussels, Belgium.
sales@obelis.net; regulatory@obelis.net
SRN #: BE-AR-000000106

Declare under the sole responsibility of Ammad Surgical that the medical device listed below meet all the provisions and requirements of the medical device regulations 2017/745 which apply to it.

Representative Device Group Category

Basic UDI-DI	Product Name	Rule	Classification	EMDN Code
++G260LIPOSU4V	Liposuction Cannulas single Use, Sterile	6	IIa	A06010103

Intended Use / Purpose: Liposuction cannulas Single Use, Sterile, used for harvesting and removing fat during Liposuction procedure. These procedures are indicated to treat “MEDICAL” conditions like lipoedema, body contour defects, scar tissue, breast reconstruction as well as “NON-MEDICAL” body contouring for aesthetic reasons, making it a “DUAL PURPOSE DEVICE”. Only the patient’s indications / intentions determine the “Medical” or “Non-Medical” use of the device. Consequently, the device is intended for Single-Procedure use within a given procedure.

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CONTACT DETAILS

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BANK DETAILS

Beneficiary: AMMAD SURGICAL
IBAN: PK66 BAH0041008100161301
SWIFT: BAHLPKAXXX
Bank: BANK AL-HABIB LIMITED
Branch: Cavalry Ground Branch.

REGISTRATION

NTN: 2700099-7
STR: 03-03-9018-005-46
LCCI: 60242-A
SIMAP: A294



The Device is classified as class IIa with the rules set out in Annex VIII of Medical Devices Regulation (EU) 2017/745; complete list of variants is attached with this DOC under Annex I.

This DOC is based on product conformity verification Part A of Annex XI of MDR with assessment of quality management system and technical file prepared in accordance to Annex II and III coupled with Section 10 or Section 18 of Annex XI.

Referring to Common Specifications for the group of products without an intended medical purpose listed in Annex XVI – Commission Implementing Regulation (EU) 2022/2346.

Regulation 2022/757 as regards harmonised standards for quality management systems, sterilisation and application of risk management to medical devices attached in Annex II of this DOC.

Additionally, the company has used MDCG guidelines referred in Annex III of this DOC.

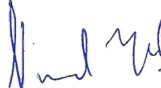
NOTIFIED BODY

Name: SGS Belgium NV
Address: SGS House – Noorderlaan 87, (RPR Antwerpen BTW BE
0404.882.750) 2030
Notified Body: 1639
Certificate Registration Number: PK25/00000147

All liposuction cannulas single use, Sterile manufactured by Ammad Surgical are in conformity with the technical documentation referred to in Annex II and III and meet the medical device Regulations which apply to it.

Technical information is kept with the manufacturer.

Lahore, Pakistan – Dated: 03/09/2025,



Signature
AMMAD NADIM
(CEO)



Signature
KHUSHBU AMMAD
PRRC

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ANNEX I

GMDN Code 36107		
SR	REFERENCE NUMBER	ITEM NAME
1	LX2L30130.H	Liposuktionskanüle mit Handgriff Liposuction Cannula with Handle Inline, 3.0 mm x 130 mm
2	LX2L30250.H	Liposuktionskanüle mit Handgriff Liposuction Cannula with Handle Inline, 3.0 mm x 250 mm
3	LX3P30250.H	Liposuktionskanüle mit Handgriff Liposuction Cannula with Handle Pyramid, 3.0 mm x 250 mm
4	LX3P40300.H	Liposuktionskanüle mit Handgriff Liposuction Cannula with Handle Pyramid, 4.0 mm x 300 mm
5	LX3P50300.H	Liposuktionskanüle mit Handgriff Liposuction Cannula with Handle Pyramid, 5.0 mm x 300 mm
6	LX5P45300.H	Liposuktionskanüle mit Handgriff Liposuction Cannula with Handle Major, 4.5 mm x 300 mm
7	LXH30250.H	Lipo-Harvester mit Handgriff Lipo-Harvester with Handle Multiport, 3.0 mm x 250 mm
8	LXH40300.H	Lipo-Harvester mit Handgriff Lipo-Harvester with Handle Multiport, 4.0 mm x 300 mm
9	LXS+40300.H	Liposuktionskanüle mit Handgriff Liposuction Cannula with Handle SpeedPlus, 4.0 mm x 300 mm
10	LXM30250.H	Liposuktionskanüle mit Handgriff Liposuction Cannula with Handle Mercedes, 3,0 mm x 250 mm
11	LXM35250.H	Liposuktionskanüle mit Handgriff Liposuction Cannula with Handle Mercedes, 3,5 mm x 250 mm
12	LXM40300.H	Liposuktionskanüle mit Handgriff Liposuction Cannula with Handle Mercedes, 4,0 mm x 300 mm
13	LXBt30250.H	Liposuktionskanüle mit Handgriff Liposuction Cannula with Handle Basket, 3,0 mm x 250 mm
14	LXBt40300.H	Liposuktionskanüle mit Handgriff Liposuction Cannula with Handle Basket, 4,0 mm x 300 mm
15	LXZ35250.H	Liposuktionskanüle mit Handgriff Liposuction Cannula with Handle Helical Tri, 3,5 mm x 250 mm

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16	LXZ45300.H	Liposuktionskanüle mit Handgriff Liposuction Cannula with Handle Helical Tri, 4,5 mm x 300 mm
17	LX2L30130.T	Liposuktionskanüle mit Gewindekonnektor Liposuction Cannula with Thread Hub Inline, 3.0 mm x 130 mm
18	LX2L30250.T	Liposuktionskanüle mit Gewindekonnektor Liposuction Cannula with Thread Hub Inline, 3.0 mm x 250 mm
19	LX3P30250.T	Liposuktionskanüle mit Gewindekonnektor Liposuction Cannula with Thread Hub Pyramid, 3.0 mm x 250 mm
20	LX3P40300.T	Liposuktionskanüle mit Gewindekonnektor Liposuction Cannula with Thread Hub Pyramid, 4.0 mm x 300 mm
21	LX3P50300.T	Liposuktionskanüle mit Gewindekonnektor Liposuction Cannula with Thread Hub Pyramid, 5.0 mm x 300 mm
22	LX5P45300.T	Liposuktionskanüle mit Gewindekonnektor Liposuction Cannula with Thread Hub Major, 4.5 mm x 300 mm
23	LXH30250.T	Lipo-Harvester mit Gewindekonnektor Lipo-Harvester with Thread Hub Multiport, 3.0 mm x 250 mm
24	LXH40300.T	Lipo-Harvester mit Gewindekonnektor Lipo-Harvester with Thread Hub Multiport, 4.0 mm x 300 mm
25	LXS+40300.T	Liposuktionskanüle mit Gewindekonnektor Liposuction Cannula with Thread Hub SpeedPlus, 4.0 mm x 300 mm
26	LXK25140.T	Kürette-kanüle mit Gewindekonnektor Curette Cannula with Thread Hub 2.5 mm x 140 mm
27	LXM30250.T	Liposuktionskanüle mit Gewindekonnektor Liposuction Cannula with Thread Hub Mercedes, 3,0 mm x 250 mm
28	LXM35250.T	Liposuktionskanüle mit Gewindekonnektor Liposuction Cannula with Thread Hub Mercedes, 3,5 mm x 250 mm
29	LXM40300.T	Liposuktionskanüle mit Gewindekonnektor Liposuction Cannula with Thread Hub Mercedes, 4,0 mm x 300 mm
30	LXBt30250.T	Liposuktionskanüle mit Gewindekonnektor Liposuction Cannula with Thread Hub Basket, 3,0 mm x 250 mm
31	LXBt40300.T	Liposuktionskanüle mit Gewindekonnektor Liposuction Cannula with Thread Hub Basket, 4,0 mm x 300 mm
32	LXZ35250.T	Liposuktionskanüle mit Gewindekonnektor Liposuction Cannula with Thread Hub Helical Tri, 3,5 mm x 250 mm

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33	LXZ45300.T	Liposuktionskanüle mit Gewindekonnektor Liposuction Cannula with Thread Hub Helical Tri, 4,5 mm x 300 mm
34	LXHTri25150.L	Harvester Triport LL Harvester Triport LL 2.5 mm x 150mm
35	LXHmi20150.L	Micro Harvester LL Micro Harvester LL 2.0 mm x 150mm
36	LXHA25200.L	Harvester Atraumatisch LL Harvester Atraumatic LL 2.5 mm x 200 mm
37	LXHM30220.L	Harvester Makro LL Harvester Macro LL 3.0 mm x 220 mm
38	LXHL30250.L	Harvester Large LL Harvester Large LL 3.0 mm x 250 mm
39	LXHS25200.L	Harvester Sharp LL Harvester Sharp LL 2.5 mm x 200 mm
40	LXK25140.L	Kürette-kanüle LL Curette Cannula LL 2.5 mm x 140 mm
41	LXi09050.L	Monoport-Kanüle, atraumatisch LL Single Port atraumatic Cannula LL 0.9 mm x 50 mm
42	LXi12070.L	Monoport-Kanüle, atraumatisch LL Single Port atraumatic Cannula LL 1.2 mm x 70 mm
43	LXi16100.L	Monoport-Kanüle, atraumatisch LL Single Port atraumatic Cannula LL 1.6 mm x 100 mm
44	LXi20150.L	Monoport-Kanüle, atraumatisch LL Single Port atraumatic Cannula LL 2.0 mm x 150 mm
45	LXi25180.L	Monoport-Kanüle, atraumatisch LL Single Port atraumatic Cannula LL 2.5 mm x 180 mm
46	LXiS20150.L	Monoport-Kanüle Spoon Tip LL Single Port Cannula Spoon Tip LL 2.0 mm x 150 mm
47	LXiS25200.L	Monoport-Kanüle Spoon Tip LL Single Port Cannula Spoon Tip LL 2.5 mm x 200 mm
48	LXV15090.L	Monoport-Kanüle V-Typ LL Single Port Cannula V-Type LL 1.5 mm x 90 mm
49	LXV20150.L	Monoport-Kanüle V-Typ LL Single Port Cannula V-Type LL 2.0 mm x 150 mm

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50	LXFp15090.L	Monoport-Kanüle Flap LL Single Port Cannula Flap LL 1.5 mm x 90 mm
51	LXFp20150.L	Monoport-Kanüle Flap LL Single Port Cannula Flap LL 2.0 mm x 150 mm
52	LXT20180.L	Tumeszenz-Infiltrationskanüle LL Tumescent Infiltration Cannula LL 2.0 mm x 180 mm
53	LXT20250.L	Tumeszenz-Infiltrationskanüle LL Tumescent Infiltration Cannula LL 2.0 mm x 250 mm
54	LXT25300.L	Tumeszenz-Infiltrationskanüle LL Tumescent Infiltration Cannula LL 2.5 mm x 300 mm
SR	REFERENCE NUMBER	ITEM NAME
55	4643	Liposuction Cannula single Port 2.0 mm x 150 mm
56	4644	Liposuction Cannula single Port 3.0 mm x 300 mm
57	4645	Liposuction Cannula Two Port 2.5 mm x 200 mm
58	4646	Liposuction Cannula Two Port 3.0 mm x 300 mm
59	4647	Liposuction Cannula Three Port 2.0 mm x 200 mm
60	4648	Liposuction Cannula Three Port 3.0 mm x 300 mm
61	4649	Liposuction Cannula Three Port 4.0 mm x 300 mm
62	4650	Liposuction Cannula One Central Two Lateral 3.0 mm x 300 mm
63	4651	Liposuction Cannula One Central Two Lateral 4.0 mm x 300 mm
64	4652	Liposuction Cannula One Central Two Lateral 5.0 mm x 300 mm
65	4653	Liposuction Cannula Mercedes 2.0 mm x 150 mm

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66	4654	Liposuction Cannula Mercedes 3.0 mm x 250 mm
67	4655	Liposuction Cannula Mercedes 3.0 mm x 300 mm
68	4656	Liposuction Cannula Mercedes 4.0 mm x 250 mm
69	4657	Liposuction Cannula Double Mercedes 4.0 mm x 250 mm
70	4658	Liposuction Cannula Double Mercedes 5.0 mm x 300 mm
71	4659	Liposuction Cannula Tripple Mercedes 5.0 mm x 300 mm
72	4660	Liposuction Cannula Single Basket 3.0 mm x 250 mm
73	4661	Liposuction Cannula Single Basket 4.0 mm x 300 mm
74	4662	Liposuction Cannula Double Basket 4.0 mm x 300 mm
75	4663	Liposuction Cannula Double Basket 5.0 mm x 300 mm
76	4664	Liposuction Cannula Double Basket 5.0 mm x 250 mm
77	4665	Liposuction Cannula Candy Cane 4.0 mm x 300 mm
78	4666	Liposuction Cannula Sattler 18 Hole 2.0 mm x 150 mm
79	4667	Liposuction Cannula Sattler 22 Hole 3.0 mm x 200 mm
80	4668	Liposuction Cannula Sattler 30 Hole 3.0 mm x 300 mm
81	4669	Liposuction Cannula Sattler 30 Hole 3.0 mm x 250 mm
82	4670	Liposuction Cannula Sattler 30 Hole 4.0 mm x 300 mm

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83	4671	Liposuction Cannula Toledo V 2.0 mm x 150 mm
84	4672	Liposuction Cannula Toledo V 3.0 mm x 250 mm
85	4673	Infiltration Cannula 10 Hole Bayonette 3.0 mm x 300 mm
86	4674	Infiltration Cannula 10 Hole Bayonette 4.0 mm x 300 mm
87	4675	Infiltration Cannula 1 Hole Spatula 2.0 mm x 150 mm
88	4676	Infiltration Cannula 30 Hole 2.0 mm x 150 mm
89	4677	Infiltration Cannula 30 Hole 2.0 mm x 250 mm
90	4678	Infiltration Cannula 30 Hole 2.0 mm x 300 mm
91	4679	Infiltration Cannula 30 Hole 3.0 mm x 250 mm

ANNEX II

Applicable Harmonized Standard	Explanation of Standard
Sterilization	
EN 556-1:2001/AC:2006	Sterilization of medical devices – Requirements for medical devices to be designated “STERILE” – Part 1: Requirements for terminally sterilized medical devices
EN ISO 11135:2014/A1:2019	Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices — Amendment 1: Revision of Annex E, Single batch release
EN ISO 11138-1:2017	Sterilization of health care products — Biological indicators Part 1: General requirements
EN ISO 11138-2:2017	Sterilization of health care products — Biological indicators — Part 2: Biological indicators for ethylene oxide sterilization processes
EN ISO 11737-1:2018/A1:2021	Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products — Amendment 1
EN ISO 11737-2:2020	Sterilization of health care products — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
ISO 11737-3:2023	Sterilization of health care products — Microbiological methods Part 3: Bacterial endotoxin testing

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EN ISO 14937:2009	Sterilization of health care products – General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices (ISO 14937:2009)
EN ISO 11607-1:2020 EN ISO 11607-1:2020/A1:2023	Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2020 EN ISO 11607-2:2020/A1:2023	Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 10993-1:2020	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
EN ISO 10993-7:2008/A1:2022	Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals — Amendment 1: Applicability of allowable limits for neonates and infants
EN ISO 10993-10:2023	Biological evaluation of medical devices — Part 10: Tests for skin sensitization
ISO 10993-12:2021	Biological evaluation of medical devices — Part 12: Sample preparation and reference materials
ISO 10993-18:2020/Amd 1:2022	Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process — Amendment 1: Determination of the uncertainty factor
ISO 14971:2019	Medical devices — Application of risk management to medical devices
ISO 15223-1:2021	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements
EN ISO 13485:2016, EN ISO 13485:2016/A11:2021	Medical devices – Quality management systems – Requirements for regulatory purposes (ISO 13485:2016)

ANNEX III

MDCG Guidelines	Short Form	Reference Number
Post Market Clinical Follow-up	PMCF	MDCG 2020-08
General Safety and Performance Requirements	GSPR	MDCG 2021-08
Periodic Safety Update Report	PSUR	MDCG 2022-21
Equivalence Table		MDCG 2020-05

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