

# **EU DECLARATION OF CONFORMITY**

We,

## Falcon Surgical Co. (Pvt) Ltd. (SRN: PK-MF-000018125)

Wazirabad Road, Village Golophala, Sialkot-51310, Pakistan.

Hereby under sole responsibility declares that below mentioned medical devices are manufactured by us have been classified according to the classification rules stated in the Chapter III of Annex – VIII and conform to the General Safety and Performance Requirements as laid out in the Annex-I of the EU MDR 2017/745 as amended by 2020/561 and the CE marking may be affixed.

#### **Device Name:**

Clamps (Non-sterile, non-active, non-measuring, reusable)

#### **Device Classification:**

Class I according to Rules 1, 1st indent set out in Chapter III of Annex-VIII, EU MDR 2017/745

## **Conformity Assessment procedure:**

Annex II, Annex III, Article 19 and Annex IV

#### **EMDN**:

Code	Description
L031307	TOWEL AND TUBE CLAMPS, REUSABLE

## **Basic Unique Device Identification (UDI-DI):**

++G120ClampsJS

## **Product List:**

Sr. #	GMDN Code(s)	Product(s) name	Product Code / Catalogue #
1.	34961	Towel clamp	Appendix L

#### Note:

Refer to the respective Summary of Technical Documentation (STED), for the product's photograph.

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## **Intended Purpose(s):**

A surgical instrument designed to hold together surgical towels and/or drapes and/or other devices, e.g., cables/leads that need securing to the site of intervention, e.g., the towels/drapes surrounding or covering the patient/operating table. It is typically made of high-grade stainless steel and can have a variety sizes and designs, e.g., it can have two blades joined at their midpoint that have ring handles at the proximal end, or it may be a single alpha-shaped part joined at the proximal end, whilst the working end may be sharply-pointed, blunted, fenestrated or have various shaped gripping jaws. It is commonly known as a towel clamp, -forceps, or a clip. This is a reusable device. For specific product please see the (Appendix L).

# Reference Regulation(s) / Standard(s) / Guidance Document(s) / Common Specification(s) (CS):

To which this declaration related is in conformity with the following standard(s) or other normative document(s)

Description	Standards/Regulation/CS
Medical devices - Quality management systems-	EN ISO 13485:2016 +
Requirements for regulatory purposes	A11:2021
Medical Device Regulation (EU) of the European	EU MDR 2017/745 as amended
Parliament and of the Council	by 2020/561
Guidance notes for manufacturers of class I medical	MDCG 2019-15 rev.1
devices	
Conformity assessment – Supplier's declaration of	EN ISO/IEC 17050-1:2010
conformity – Part 1: General requirements	
Medical devices-Application of risk management to	EN ISO 14971:2019 +
medical Devices	A11:2021
Medical Devices - Symbols to be used with medical	EN ISO 15223-1:2021-07
device labels, labeling and information to be supplied	
part-1 –General requirement	
Medical devices - Symbols to be used with medical	EN ISO 15223-2:2010
device labels, labeling, and information to be supplied –	
Part 2: Symbol development, selection and validation	
Medical devices — Information to be supplied by the	EN ISO 20417:2021
manufacturer	
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Description	Standards/Regulation/CS
Biological evaluation of medical devices, part 1:	EN ISO 10993-1:2020
evaluation and testing within a risk management process	
Biological evaluation of medical devices, part 18:	EN ISO 10993-18:2020
chemical characterization of medical device materials	
within a risk management process	
Standard Specification for Wrought Stainless Steel for	ASTM F899-20
Surgical Instruments	
Surgical Instruments – Metallic Materials – Part 1:	EN ISO 7153-1:2016
Stainless Steel	
Surgical and Dental Hand Instruments – Determination	EN ISO 13402:2000
of resistance against autoclaving, corrosion and thermal	
exposure	
Standard Test Method for Corrosion of Surgical	ASTM F1089-18
Instruments	
Metallic materials – Rockwell hardness test – Part 1:	EN ISO 6508-1:2016
Test method	
Clinical evaluation – guide for manufacturer and notified	MEDDEV 2.7/1 Rev.4
bodies	
Guidance on clinical evaluation – Equivalence	MDCG 2020-5
Guidance on sufficient clinical evidence for legacy	MDCG 2020-6
devices	
Post-marketing surveillance (PMS) Recommendation	NB-Med 2_12-1_rev11
Guidance on a Medical devices vigilance system	MEDDEV 2.12/1 rev.08
Sterilization of health care products - Moist heat - Part 1:	EN ISO 17665-1:2006
Requirements for the development, validation and routine	
control of a sterilization process for medical devices	
Processing of health care products – Information to be	EN ISO 17664-1:2021
provided by the medical device manufacturer for the	

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Description	Standards/Regulation/CS
processing of medical devices - Part 1: Critical and semi-	
critical medical devices	
Dentistry - Medical devices for dentistry - Instruments	EN 1639:2009
Dentistry – Materials for dental instruments – part 1:	EN ISO 21850-1:2020
Stainless Steel	

We have prepared and maintained technical documentation for each device(s) as required by Annex II & III of EU MDR 2017/745 as amended by 2020/561. The records are maintained for 10 years.

# **EU AUTHORIZED REPRESENTATIVE (EUAR):**

CMC MEDICAL DEVICES & DRUGS, S.L (SRN: ES-AR-000000293)

C/ Horacio Lengo n18

C. P 29006

Málaga-Spain

Phone: +34 951 214 054

Email: <u>info@cmcmedicaldevices.com</u>

Notified Body Details: Not applicable

Signed for and on behalf of: Falcon Surgical Co. (Pvt) Ltd.

Signature:	April 1
Name:	Muhammad Usman
<b>Designation:</b>	PRRC
Place of Issue:	Wazirabad Road, Village Golophala, Sialkot-51310, Pakistan.
Date of Issue:	21-02-2023

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# FALCON SURGICAL CO. (PVT) LTD.

Wazirabad Road, Village Golophala, Sialkot-51310- Pakistan.

## LIST OF PRODUCTS

Clamps

(Non-sterile, non-active, non-measuring, reusable)

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Sr. #	Catalogue Code	Instruments Included	<b>Intended Purpose</b>
1.	BF.407.090	Forceps towel Jones 90mm	A surgical instru
2.	BF.411.090	Forceps towel Schaedel 90mm	together surgical to
3.	BF.431.090	Forceps towel Backhaus 90mm	other devices, e.g.
4.	BF.431.110	Forceps towel Backhaus 110mm	securing to the site
5.	BF.431.130	Forceps towel Backhaus 130mm	towels/drapes surro
6.	BF.431.150	Forceps towel Backhaus 150mm	patient/operating tal
7.	BF.511.095	Forceps towel Devon (ball and socket) non-tearing 95mm	high-grade stainles variety sizes and des
8.	BF.511.105	Forceps towel Devon (ball and socket) non-tearing 105mm	blades joined at the handles at the prox
9.	BF.511.115	Forceps towel Devon (ball and socket) non-tearing 115mm	single alpha-shape proximal end, whils
10.	BF.511.130	Forceps towel Devon (ball and socket) non-tearing 130mm	sharply-pointed, blu various shaped grip
11.	BF.511.140	Forceps towel Devon (ball and socket) non-tearing 140mm	known as a towel control of the transfer of th
12.	DZ.945.020	Towel chain metal	
13.	DZ.945.050	Smile towel holder	
14.	CAF015	Towel holder metal	
15.	COX010	Towel chain metal	
16.	DZ.935.010	Towel holder metal	
17.	DZ.945.010	Towel chain rubber	
18.	SS.616.025	Clip Small Serrated 25mm	
19.	SS.616.065	Clip multi-purpose serrated 65mm	
20.	2S02138	Forceps towel Backhaus 90mm	
21.	BF.407.055	Forceps towel Jones 55mm	
22.	BF.408.090	Forceps towel English Pattern 90mm	
23.	BF.421.180	Forceps towel Doyen 180mm	
24.	BF.425.190	Forceps towel Moynihan 190mm	
25.	BF.439.135	Forceps towel Roeder 135mm	1
26.	BF.439.150	Forceps towel Roeder 150mm	1
27.	BF.450.160	Forceps towel Bernhard 160mm	1
28.	BF.461.110	Forceps towel Backhaus with clip	
29.	BF.465.135	Forceps towel Robin with clip 5mm, 135mm	
30.	BF.467.135	Forceps towel Robin with clip 13mm, 135mm	
31.	BF.468.135	Forceps towel Robin with clip 25mm, 135mm	

A surgical instrument designed to hold together surgical towels and/or drapes and/or other devices, e.g., cables/leads that need securing to the site of intervention, e.g., the towels/drapes surrounding or covering the patient/operating table. It is typically made of high-grade stainless steel and can have a variety sizes and designs, e.g., it can have two blades joined at their midpoint that have ring handles at the proximal end, or it may be a single alpha-shaped part joined at the proximal end, whilst the working end may be sharply-pointed, blunted, fenestrated or have various shaped gripping jaws. It is commonly known as a towel clamp, -forceps, or a -clip. This is a reusable device.

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# FALCON SURGICAL CO. (PVT) LTD.

Wazirabad Road, Village Golophala, Sialkot-51310- Pakistan.

# LIST OF PRODUCTS

Clamps (Non-sterile, non-active, non-measuring, reusable)

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32.	BF.481.100	Forceps towel Lorna non-tearing
		100mm
33.	BF.481.130	Forceps towel Lorna non-tearing
		130mm
34.	BF.481.140	Forceps towel Lorna non-tearing
		140mm
35.	BF.491.135	Forceps towel Falcon non-tearing
		135mm
36.	BF.495.145	Forceps towel Peers non-tearing
		145mm

**Signature:** 

Name: Muhammad Usman

Designation: PRRC

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