

Description	Standards/Regulation/CS
Biological evaluation of medical devices, part 1: evaluation and testing within a risk management process	EN ISO 10993-1:2020
Biological evaluation of medical devices, part 18: chemical characterization of medical device materials within a risk management process	EN ISO 10993-18:2020
Standard Specification for Wrought Stainless Steel for Surgical Instruments	ASTM F899-20
Surgical Instruments – Metallic Materials – Part 1: Stainless Steel	EN ISO 7153-1:2016
Surgical and Dental Hand Instruments – Determination of resistance against autoclaving, corrosion and thermal exposure	EN ISO 13402:2000
Standard Test Method for Corrosion of Surgical Instruments	ASTM F1089-18
Metallic materials – Rockwell hardness test – Part 1: Test method	EN ISO 6508-1:2016
Clinical evaluation – guide for manufacturer and notified bodies	MEDDEV 2.7/1 Rev.4
Guidance on clinical evaluation – Equivalence	MDCG 2020-5
Guidance on sufficient clinical evidence for legacy devices	MDCG 2020-6
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: Requirements for the development, validation and routine control of a sterilization process for medical devices	EN ISO 17665-1:2006
Processing of health care products – Information to be provided by the medical device manufacturer for the	EN ISO 17664-1:2021

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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: Stainless Steel	EN ISO 21850-1:2020

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):

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Notified Body Details: *Not applicable*

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

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

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	Intended Purpose
1.	BF.407.090	Forceps towel Jones 90mm	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.
2.	BF.411.090	Forceps towel Schaedel 90mm	
3.	BF.431.090	Forceps towel Backhaus 90mm	
4.	BF.431.110	Forceps towel Backhaus 110mm	
5.	BF.431.130	Forceps towel Backhaus 130mm	
6.	BF.431.150	Forceps towel Backhaus 150mm	
7.	BF.511.095	Forceps towel Devon (ball and socket) non-tearing 95mm	
8.	BF.511.105	Forceps towel Devon (ball and socket) non-tearing 105mm	
9.	BF.511.115	Forceps towel Devon (ball and socket) non-tearing 115mm	
10.	BF.511.130	Forceps towel Devon (ball and socket) non-tearing 130mm	
11.	BF.511.140	Forceps towel Devon (ball and socket) non-tearing 140mm	
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	
26.	BF.439.150	Forceps towel Roeder 150mm	
27.	BF.450.160	Forceps towel Bernhard 160mm	
28.	BF.461.110	Forceps towel Backhaus with clip 110mm	
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	

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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