KONFORMITÄTSERKLÄRUNG / DECLARATION OF CONFORMITY

EU - Declaration Of Conformity

We **SURGIVALLEY PVT LTD**, declare on our own responsibility that the Medical Device(s).

Sr No.	Device Name	Intended use/purpose of the device
1	EXPLORER	DENTAL
2	ELEVATORS	DENTAL/SURGICAL/ORTHOPEDIC / SPINE
3	EXPLORER	DENTAL/SURGICAL/ORTHOPEDIC / SPINE
4	KNIFE	DENTAL/SURGICAL/ORTHOPEDIC / SPINE
5	MOUTH GAGS	DENTAL/SURGICAL/ORTHOPEDIC / SPINE
6	NEEDLE HOLDERS	DENTAL/SURGICAL/ORTHOPEDIC / SPINE
7	PLIERS	DENTAL/SURGICAL/ORTHOPEDIC / SPINE
8	PUNCHES	DENTAL/SURGICAL/ORTHOPEDIC / SPINE
9	RETRACTOR	DENTAL/SURGICAL/ORTHOPEDIC / SPINE
10	SCALER	DENTAL/SURGICAL/ORTHOPEDIC / SPINE
11	SPATULA	DENTAL/SURGICAL/ORTHOPEDIC / SPINE
12	SPREADER	DENTAL/SURGICAL/ORTHOPEDIC / SPINE
13	SUCTION TUBES	DENTAL/SURGICAL/ORTHOPEDIC / SPINE
14	SYRINGES	DENTAL/SURGICAL/ORTHOPEDIC / SPINE
15	ALUMINIUM HAND	ORTHOPEDIC
16	ADAPTERS	ORTHOPEDIC / SPINE
17	BLADEHOLDERS	ORTHOPEDIC / SPINE

18	BONE CUTTER	ORTHOPEDIC / SPINE
19	BONE FILE	ORTHOPEDIC / SPINE
20	BONE LEVELER SAW	ORTHOPEDIC / SPINE
21	BURRS	ORTHOPEDIC / SPINE
22	CALIPERS	ORTHOPEDIC / SPINE
23	CHOPPERS	ORTHOPEDIC / SPINE
24	DISSECTORS	ORTHOPEDIC / SPINE
25	DRILLS	ORTHOPEDIC / SPINE
26	EXTRACTORS	ORTHOPEDIC / SPINE
27	GAUGES	ORTHOPEDIC / SPINE
28	INSTRUMENTATION-KITS	ORTHOPEDIC / SPINE
29	KWIRES	ORTHOPEDIC / SPINE
30	MALLETS	ORTHOPEDIC / SPINE
31	MICROSURGICAL	ORTHOPEDIC / SPINE
32	NERVEROOT-RETRACTORS	ORTHOPEDIC / SPINE
33	OSTEOTOMES	ORTHOPEDIC / SPINE
34	RONGEURS	ORTHOPEDIC / SPINE
35	ROUNGEURS	ORTHOPEDIC / SPINE
36	SHIELDS	ORTHOPEDIC / SPINE
37	CONTAINERS	SURGICAL
38	DILATORS	SURGICAL
39	ISOLATION GOWN	SURGICAL
40	TRAYS	SURGICAL
41	TWEEZER	SURGICAL
42	ASPIRATORS	SURGICAL/ORTHOPEDIC / SPINE

43	BIOPSI KITS	SURGICAL/ORTHOPEDIC / SPINE
44	CHISELS	SURGICAL/ORTHOPEDIC / SPINE
45	CLAMPS	SURGICAL/ORTHOPEDIC / SPINE
46	CURETTE	SURGICAL/ORTHOPEDIC / SPINE
47	DILATORS	SURGICAL/ORTHOPEDIC / SPINE
48	EXCAVATORS	SURGICAL/ORTHOPEDIC / SPINE
49	FORCEPS	SURGICAL/ORTHOPEDIC / SPINE
50	HOOKS	SURGICAL/ORTHOPEDIC / SPINE
51	PROBES	SURGICAL/ORTHOPEDIC / SPINE
52	SCALPEL HANDLES	SURGICAL/ORTHOPEDIC / SPINE
53	SCISSORS	SURGICAL/ORTHOPEDIC / SPINE
54	SPOONS	SURGICAL/ORTHOPEDIC / SPINE
55	TREPHINES	SURGICAL/ORTHOPEDIC / SPINE
56	TROCARS	SURGICAL/ORTHOPEDIC / SPINE
57	TUBES	SURGICAL/ORTHOPEDIC / SPINE

are **Class 1R Medical Devices** (Reusable Surgical Instruments) and meets according to **Annex VIII of Medical Devices Directive**.

The products fulfill all the technical requirements listed in the **Annex II** & **Annex III** of the **Medical Devices Regulations MDR 2017/745**. Conformity assessment was carried out on the basis of the **Annex IX** of the **Council MDR 2017/745**.

Rule: Rule 6 *(All surgically invasive devices intended for transient use are in Class IR if they are reusable instruments)*

Branded UMS products, and model names with prefix 60,70,80, SV and UMS are manufactured by Surgivalley and under Surgivalleys sole responsibility

The Technical File is maintained at:

Surgivalley Pvt. Ltd. , 143-C, SMALL INDUSTRIAL ESTATE, SHAHABPURA ROAD, SIALKOT-51310, PAKISTAN

Phone: +92523556777

Email: info@surgivalley.com

Whereas our all products are manufactured under the guidelines of following international standards:

Standard	Description
ISO-13485:2016	Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes
ISO-9001:2015	Quality Management System - Requirements
MDR 2017/745	Council Regulations for Medical Devices
ASTM F899-12b	Standard Specification for Wrought Metals for Surgical Instruments
ISO 14971:2012	Medical devices Application of risk management to medical devices
BS.EN-1041:2008	Information Supplied by the Manufacturer with Medical Devices
EN 62366:2008	Medical devices — Application of usability engineering to medical devices
ISO-7153-1:2016	Surgical Instruments – Materials – Part 1: Metals
ISO-17664:2004	Sterilization of Medical Devices – Information to be provided by the manufacturer for the processing of re-sterilization medical devices
BS EN ISO 15223-1:2012	Symbols to be used in the labeling of medical devices
cGMP	Current Good Manufacturing Practices

Risk Classification: Low Risk Devices

Manufacturing Site: **SURGIVALLEY PVT. LTD.**

143-C, SMALL INDUSTRIAL ESTATE, SHAHABPURA ROAD, SIALKOT-51310, PAKISTAN

EC REP

MAXCERT

Heidelbergerstrasse 79, 69190 Walldorf, Germany

SURGIVALLEY
Proprietor

01-04-2022
Ausstellungdatum/ Date of issue

CEO (Surgivalley Pvt Ltd)
Signature