



WITTEX International

MANUFACTURERS & EXPORTERS OF FINE QUALITY SURGICAL, DENTAL AND SINGLE USE INSTRUMENTS



EC Declaration of Conformity

Non-Sterile, Reusable, Dental Instruments

Manufacturers Name: Wittex International

Manufacturers Address: Wazirabad Road, Harar, Sialkot – Pakistan.

Authorized Representative Name: Obelis S.A

Authorized Representative Address: Bd. General Wahis, 53
1030 Brussels,
Belgium
Tel: +32 2 732 5954
Email: mail@obelis.net

SRN No: PK-MF-000022939

Name of the Device (s): Please see attached product list

Product code: Please see attached product list

Classification: Class I

Notified Body name: Not Applicable

Notified Body Address: Not Applicable

Notified Body Identification number: Not Applicable

Applicable Standards ISO 15223-1:2021, ISO 20417:2021, ISO 14971:2019

Conformity assessment route: Wittex International uses the following procedures for the CE-labeling of their products according the Regulation MDR 2017/745:

This declaration of conformity is issued under the sole responsibility of Wittex International. We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices. This declaration is supported by the Quality System approval to ISO 13485 issued by SGS.

All supporting documentation is retained at the premises of the manufacturer.

Signature:

Ch. Shahid Mehmood
CEO

Place and date of issue:

Wazirabad Road, Harar, Sialkot – Pakistan.
20/12/2023

Doc #: DoC-14, Rev 01

Page 1 of 3

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ISO 9001 : 2015
ISO 13485: 2016
cGM FDA Approved.



Sr. #	Catalog #	Product Description
1.	728/2	Tweezers
2.	1085/8	Sondes
3.	871B/13	Scalpel Blades Box
4.	623A	Servietenhalter
5.	U8991	Ainsworth
6.	U8987	Palmer
7.	871/A3	Scalpel Handles
8.	483	Mirror Handles
9.	826	Crown scissors
10.	828	Crown scissors
11.	829	Crown scissors
12.	1061/6	Filing instruments
13.	12	Filing instruments
14.	U8872	Molar Stofir
15.	9215-16	Ivanson
16.	U9207	Articulations
17.	9397 L-2	Endodontics Trays
18.	9400	Seringe Casse 2ml,P4
19.	9400	Seringe Casse 2ml,P4
20.	U7812	Fig 2 Elevators
21.	U7814	Fig 4R Elevators
22.	U7569	Extrating Forceps Fig.8





Sr. #	Catalog #	Product Description
23.	U7584	Extrating Forceps Fig.31
24.	U7656	Extrating Forceps Fig.39L
25.	U7660	Extrating Forceps Fig.75
26.	U7640	Extrating Forceps Fig.51A
27.	U7600	Extrating Forceps Fig.52A
28.	3040-1	Ruberdam Frame Stainels(10X10)
29.	0480-1	Dental Syringes
30.	0480-2	Dental Syringes
31.	2465/1	Separators 12 bads
32.	2465/4	Separators 12 bads

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