

DECLARATION OF CONFORMITY

DOC-01-01
April, 08, 2022

We,
Acme Commercial Ways(Pvt)Ltd.
Nowl More Roras Road, P.O.Box 1092,
Sialkot 51310 Pakistan.

Declare under our sole responsibility that the product(s)

**Micro Scissors, Scissors, Anatomical Tweezers, Surgical Forceps, Pump Nozzl,
Surgical Hooks, Retractors etc (Non Sterile)**

To which This declaration relates is in conformity with the following standard(s) or other normative standards(s)

Following all the provisions of Medical Device Rules 2017/745, Conformity Route Adopted is according To Annexure VII and the device is "Class I" under Rule 5 of annexure VIII (Invasive thru body orifice for transient use).

ISO 9001:2015
EN ISO 14971:2012
Medical Device Directive 93/42/EEC as updated 2007/47/EC.
EN ISO 13485: 2016
ISO 15223-1:2016
EN ISO 10993-1:2018
EN ISO10993-2:2006
EN ISO10993-3:2014
EN 1041:2008
ISO 15223-2:2010
EN 980:2008
MEDDEV 2.12. /2 Rev.02, January 2012
MEDDEV 2.5. /10, January 2012
MEDDEV 2.4/1 Rev-09, June 2010

MEDDEV 2.7.1 Rev.03, December 2009
MEDDEV 2.7.1 Appendix-1, December 2008
MEDDEV 2.12.1 Rev.08, Mars 2012
EN ISO 62366: 2008
NBOG 2010-1
ASTM F899-12
ISO 7153-1:2016
ISO 17665-1:2006
ISO 11135-1:2014

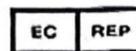


This declaration is valid until a new revision is issued.



Director

Place: Sialkot-Pakistan Date: 08-04-2022



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