

## EC DECLARATION OF CONFORMITY

We,

**Manufacturer's Name: Associated Products Company**

**Address: Small Industrial Estate, Mustafa Town, P.O. Box No 1802, Sialkot-51310-Pakistan**

**Email ID: [info@associated.com.pk](mailto:info@associated.com.pk)**

Hereby under sole responsibility declares that below mentioned medical devices manufactured by us have been classified as Class I according to the classification rules stated in the Chapter III of Annex – IX and conform to the Essential Requirements as laid out in the Annex-I of the EU MDD 93/42/EEC as amended by 2007/47/EC and the CE marking may be affixed.

### **Conformity Assessment procedure:**

Annex I and Annex VII of EU MDD 93/42/EEC as updated by 2007/47/EC.

### **Medical Device Name:**

Non-sterile, reusable, non-active Surgical and Dental Instruments

### **List of Products:**

➤ **See List of Instruments (Annex I- Agreement 210521/177)**

This declaration related is in conformity with the following standard(s) used or other normative document(s) / guideline(s)

ISO 9001 Quality Management Systems

ISO 13485 Medical Devices – Quality Management Systems – Requirements for Regulatory Purpose

MDD 93/42/EEC as amended 2007/47/EC Council Directive for Medical Devices

Doc #	DOC-APC-01	Rev. #	00	Page #	Page 1 of 2
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### **Head Office**

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Tel: 92-52-3558764 / 3562133 Fax: 92-52-3552964 / 3562964  
E-mail: [info@associated.com.pk](mailto:info@associated.com.pk) / [associa@brain.net.pk](mailto:associa@brain.net.pk)

### **Liaison Office for EU**

M. Sarwar (Chief Sales Executive)  
Van Swietenstraat 25, 2518 SC The Hague. The Netherlands  
Tel: +31 70 3654402 Fax: +31 70 3654402 Cell: +31 654 266224  
E-mail: [sarwar@ziggo.nl](mailto:sarwar@ziggo.nl)

ISO 14971	Medical Devices—Application of Risk Management to Medical Devices
ISO 17664	Sterilization of Medical Devices – Information to be provided by the manufacturer for the processing of re-sterilizable medical devices
ISO 15223-1	Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied part-1 – general requirements
cGMP	Medical Devices – Current Good Manufacturing Practices
ASTM-F899	Standard Specification for Stainless Steel Billet, Bar, and Wire for Surgical Instruments
ISO 7153-1	Surgical Instruments – Metallic Materials – Part 1: Stainless Steel
ISO 21850-1	Dentistry – Materials for dental instruments – part 1: Stainless Steel

We prepare and maintain technical documentation for each device as requires by applicable classification rules and Annex-VII of the directive. Records are maintained for 10 years.

We have appointed the EU Authorized Representative as below:

**CMC MEDICAL DEVICES & DRUGS, S.L.**

C/ Horacio Lengo n18  
C. P 29006  
Málaga-Spain  
Tel: +34 951 214 054  
Email: [info@cmcmmedicaldevices.com](mailto:info@cmcmmedicaldevices.com)

**Signed for and on behalf of: Associated Products Company**

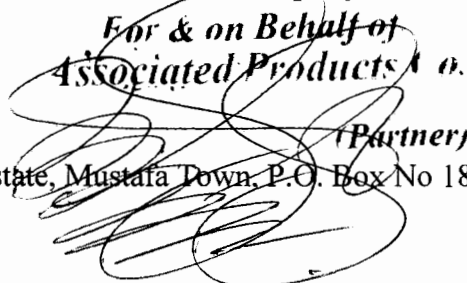
**Name:** Shahzad Bashir Ahmed

**Designation:** CEO

**Place of Issue:** Small Industrial Estate, Mustafa Town, P.O. Box No 1802, Sialkot-51310-Pakistan

**Date of Issue:** 21-05-2021

*For & on Behalf of*  
**Associated Products Co.**  
*(Partner)*



Doc #	DOC-APC-01	Rev. #	00	Page #	Page 2 of 2
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Art.	Bezeichnung	Fremd-Nr.
1118	Nagelschere 10 cm mit gebogener Schneide	016-179
1119	Nagelschere 9 cm mit gerader Schneide	016-187
1120	Hautschere 10 cm mit gerader Schneide	016-184
1121	Hautschere 10 cm mit Turmspitze	016-181
1125	Storchenschere 9 cm rostfrei	016-132
1130	Verbandschere 14 cm mit gerader Schneide	012-1131
1140	Flach-Pinzette schräg	016-161
1150	Skalpellhalter-3- f. Klingen 10-15	010-563
1150H	Skalpellhalter-3- f. Klingen 10-15, Hohlinstrument	010-470H
1151	Skalpellhalter-4- f. Klingen 18-23	010-564
1151H	Skalpellhalter-4- f. Klingen 18-23, Hohlinstrument	010-468H
1153	Medihalter, rostfrei für Hohlmeißelklingen	09-751
1160	Doppelsonde / Excavator spitz	09-711
1163	Greifpinzette, 15 cm rostfrei	010-588
1164H	PEDICE Nageleckenfeile doppelt 15 cm, Hohlgriff	07-571H
1165	Wattehaken, 15 cm rostfrei	09-800
1166	PEDICE Doppelsonde / Excavator rund	09-579
1166H	PEDICE Doppelsonde / Excavator rund, Hohlgriff	09-579H
1167	Doppelsonde DS 14,5 cm, Diabetic Safe	09-579 SD
1169	Löffelinstrument DS 14,5 cm, Diabetic Safe	09-578 SD
1170	Löffelinstrument, mittel doppelt, rostfrei	09-578
1170H	Löffelinstrument mit Hohlgriff, doppelt, rostfrei	09-578
1189	Splitterpinzette 11,5 cm	010-565
1198	Doppelinstrument, rostfrei, 16 cm	09-544
1200	PEDICE Instrumentenablage, Edelstahl	013-111
1414	PEDICE Eckenzange 11,5 cm klein mit runder Schneide	03-316
1417	PEDICE Eckenzange 13 cm mit spitzer Schneide	03-328
1419	PEDICE Hautzange 10 cm mit Scherengriff	0-609
1425	PEDICE Nagelzange 14 cm mit Puffer-Feder	03-374
1429	PEDICE Eckenzange 11,5 cm mit schmaler, langer Spitze	03-394
1452	PEDICE Hautzange DS DiabeticSafe 10 cm, 5 mm Schneide	SD 0-556 5 mm
1470	PEDICE Hautzange 10,5 cm mit 3 mm Schneide	0-556 3-mm
1475	PEDICE Hautzange 10,5 cm mit 5 mm Schneide	0-556 5-mm
1476	PEDICE Hautzange 11 cm mit 6 mm Schneide	0-556 6-mm
1477	PEDICE Hautzange 11 cm mit 8 mm Schneide	0-556 8-mm
1485	PEDICE Nagelzange 13 cm gewölbte Schneide	03-358
1487	PEDICE Nagelzange 13 cm mit gerader Schneide	03-318
1490	PEDICE Kopfschneider 13,5 cm mit ganzer Schneide	01-247
1491	PEDICE Kopfschneider 14 cm halbe Schneide	01-237
1495	PEDICE SHORT CUT SOFT Nagelzange 12 cm	1495
1519	Komedonenschlinge zweifach	014-126
1521	Komedonenheber feine Schlinge	014-132
1523	PEDICE Pinzette, gerade	016-309
1524	PEDICE Pinzette, gewinkelt	016-305
1525	PEDICE Pinzette, schräg	016-301
1604	Hornhauthobel, Edelstahl für Credoklingen	015-117
2410	B/S Applikator Edelstahl, rostfrei	09-583