

October 13, 2020

EC Declaration of Conformity

We,

MESSRS. UK-PAK DENTAL,

Airport road, Gohad pur, Mughal Pura Block B, Street No. 1 Sialkot - Pakistan. Tel: 0092- 300 6106081 Fax: 0092-52-4563734 Email: <u>ukpakdent@gmail.com</u> URL: <u>http://www.ukpakdental.com</u>

Hereby declare that we fall within manufacturers of Class – I devices and the devices produced by us are

Dental dam metal frames + Dental dam clamp organizer (Dental Instruments)

Meet the essential requirement of Directive No. 93/42/EEC as amended by directive 2007/47/EEC. We prepare and maintain technical documentation for each device as requires by Annes-Annex-I and VII of the directives.

To which the declaration related is in conformity with the following standard(s) or other normative document(s)

ISO 9001:2015 & ISO 13485:2016	Quality Management Systems
cGMP	Medical Devices; Current Good Manufacturing Practice
93/42/EEC	Council Directive for Medical Devices

For

M Berner

Our Authorized Representative in, EU

RoyalCert International Registrars GmbH Friedrich-Ebert-Anlage 36, 60325 Frankfurt am Main, Deutschland T : +49 69 257 129 81 Email: info@royalcert.com