10 Ranick Road
Hauppauge, NY 11788-4209
Tel: 888-276-7783 I Fax: 631-582-1726
Crosstex.com

EU Medical Device Directive
93/42/EEC as Amended by 2007/47/EC
Declaration of Conformity

Manufacturer:	Crosstex International, Inc.	EU Representative:	MDSS GmbH
Address:	10 Ranick Road Hauppauge, NY 11788	Address:	Schiffgraben 41 30175 Hannover Germany

Product(s): Dentapure Waterline Purification Cartridges

Model(s): DPI365M – 365-day Municipal Cartridge
DPI365B – 365-day Independent Water Bottle Cartridge

GMDN: 61138

Assessment of Product Based Upon:

Quality System Certification	ISO 13485 Certificate No: MD19.4439 Issued By: NSAI (0050)
CE Certification	CE Certificate No: 252.1151.00 Conformity Assessment Route: Annex II
Notified Body: Address:	National Standards Authority of Ireland, NSAI (0050) 1 Swift Square, Northwood, Santry, Dublin 9, Ireland
Essential Requirements Checklist	Prepared by: Regulatory Affairs
Technical File	Prepared by: Regulatory Affairs

Product Classification: Product classification based on the requirements of MDD Annex IX and EU Guidelines for Classification of Medical Devices MEDDEV 2.4.

- ☐ Class I
- ☒ Class IIa per Rule 15
- ☐ Class IIb
- ☐ Class III

Based on a review of the above documents, we, the manufacturer, hereby declare that the above product complies with the requirements of the EC Directive 93/42/EEC as amended by 2007/47/EC.

Approved by:

Pablo Martinez

7/31/2019

Pablo Martinez
Senior Regulatory Affairs Manager

Date