POLYBOND INDIA PVT. LTD.

Doc No.: TF-ECD-10
Revision No.: 00
Date: 10.12.2020

EC DECLARATION OF CONFORMITY

According to annex –II of the MDD 93/42/EEC & by amended directive 2007/47/EC concerning medical devices we:

Polybond India Pvt. Ltd.
Gat No. 1088, Pimple Jagtap Link Road, Sanaswadi, Tal Shirur, Dist Pune, Maharashtra, India 412208

Declare under our sole responsibility that the product:

S. No.	Device Name	Brand Name	Size/Variants	Rule	Class
1	BT Set	Ecotran-V, Ecotran-NV	Vented / Non Vented	7	IIa

Meets the provisions of the MDD 93/42/EEC & by amended directive 2007/47/EC concerning medical devices which apply to them:

The MD is in **Class IIa**, according to annex-IX of the Medical Device Directive and certified as per article 11.3 (a). We have presented our product as well as our quality management system to the Notified Body (**DNV GL Presafe AS-NB No. 2460)** for assessment as per the requirements of MDD 93/42/EECas amended by 2007/47/EC.Following standards were used to prove the products conformity with the essential requirements of the Directive:

Applicable Standards: [EN ISO 14971: 2012],[EN ISO 14155 : 2011], [EN ISO 10993-1: 2009/AC:2010],[EN ISO 10993-3:2014],[EN ISO 10993-4: 2009],[EN ISO 10993-5 : 2009],[EN ISO 10993-7: 2009],[EN ISO 10993-10:2013],[EN ISO 10993-11:2009],[EN ISO 10993-12 :2012],[EN ISO 10993-13:2010],[EN ISO 10993-15:2009],[EN ISO 10993-16:2010],[EN ISO 10993-17:2009],[EN ISO 10993-18:2009],[EN ISO 11607-1:2009],[EN ISO 11607-2:2006],[ISO 9001:2015],[EN ISO 13485:2016],[ISO 14644 -1 : 2015],[ISO 14644 -2 : 2015],[ISO 14644 -8: 2013],[ISO 14644 -9 : 2012],[ISO 14644 -10 : 2013],[EN ISO 11737-1 :2006/AC:2009],[EN ISO 11737-2:2009],[EN ISO 11140- 1 :2009],[ISO 11138- Part 1&2 :2009], [EN 1041:2008],[EN ISO 15223:2016], [EN ISO 11135:2007],[ISO 9626:1991/Amd 1:2001],[EN 62366:2015],[ISO 1135-4:2015], [ISO 7864:2016],
[ISO 2859-1:1999], IP, USP of latest Edition.

Signatory established within the EU who has been empowered to enter into commitments our behalf:

NOTIFIED BODY:

DNV GL Presafe AS
Veritasveien 3, 1363 Høvik, Norway

NOTIFIED BODY NO: 2460

CE Certificate No: **245045-2017-CE-IND-NA-PS Rev 1.0**
Date of Issue: 16-**January-2020**
Valid till: **09 January 2024**

CE **2460**

EC REP : **CMC Medical Devices & Drugs S.L.**
C/ Horacio Lengo Nº 18, CP 29006,
Málaga, Spain.Ph +34951214054
Email info@cmcmedicaldevices.com
Web www.cmcmedicaldevices.com

POLYBOND INDIA PVT. LTD. SANASWADI

Authorized Signatory

Karunesh Mishra
(D.G.M.-Operations)