TURQUOISE BIOMEDICAL TECHNOLOGIES

93/42/EEC DECLARATION OF CONFORMITY

We hereby declare that below listed products are in conformance with 93/42/EEC conditions. All necessary documents are held within the premises of manufacturer.

Company Name	**:** Turkuaz Biyomedikal Teknoloji ve Sağ. Hiz. San. ve Tic. Ltd. Şti.
Address	**:** Kazım Özalp Mah. Hafta Sok. No: 23/2 06610 Çankaya / ANKARA / TURKEY
Tel / Fax	**:** +90 850 840 8 828 / +90 312 911 25 28
Web / E-mail	**:** www.tbtmedical.com / info@tbtmedical.com
Product	**:** Sterilization Process Indicators
Model	**:** PLUSAFE Series
GMDN Code	**:** 35362
Classification	**:** Class I according to Medical Devices Directive 93/42/EEC, Annex VII
Applied Standards	**:** EN 868-5, EN ISO 11140-1, EN ISO 11607

We declare that *Bowie-Dick Test Packs, Class 6 Emulating Indicator, Class 4 Multi-Variable Indicator, H2O2 Gas Plasma Indicator, Container Registration Card with Indicator, Adhesive Tape with Indicator, Bowie-Dick Helix Test and Batch Control Helix Test* "Sterilization Process Indicators" are complying 93/42/EEC Medical Devices Directive's requirements.

TURKUAZ BİYOMEDİKAL TEKNOLOJİLER
VE SAĞ. HİZ. SAN. TİC. LTD. ŞTİ.
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M. Hilmi MİRELİ
CEO

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02/01/2018