CE Technical File Sterile Tube Welder

File No:

Rev. No: A/0

Declaration of Conformity

Manufacturer:

Wuhan bms Medicaltech Co.,Ltd.

Address: No. 3 & 4, 5th Floor, B9, Phase I, Block B, Hi-tech Medical

Devices Park, 818 Gaoxin Avenue, East Lake High-tech Development Zone, Wuhan, China (Wuhan Free Trade Zone)

European

MedUnion S.L.

Representative:

Address: Carrer de Tapioles, 33, 2-1, Barcelona, 08004, Spain

SRN: ES-AR-000019366 Tel: +34 644173535

Email: rep@themedunion.com

Product Name:

Sterile Tube Welder

Models:

STW6810-RFID

UDI-DI: 6976052440092

Classification (MDR, Annex VIII): I / Rule 13

Conformity Assessment Route: Annex IX, MDR (2017/745)

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Regulations and Standards. All supporting documentations are retained under the premises of the manufacturer. We are exclusively

responsible for the Declaration of Conformity.

General applicable regulations:

Medical Device Regulation: MDR (2017/745).

Signature:

Name:

Position:

Alech Co. F. F.

General Manager