BIÇAKCILAR
TIBBİ CİHAZLAR SANAYİ VE TİCARET A.Ş.

02.11.2022

To whom it may concern,

Medical Devices classified as Class I could be marketed with declaration of conformity according to Medical Device Directive 93/42/EEC, Article 11 Conformity assessment procedures Clause.5, which is stated as below. Having ISO13485 Medical devices — Quality Management Systems certificate is required instead of EC Certificate.

Article 11

Conformity assessment procedures

5. In the case of devices falling within Class I, other than devices which are custom-made or intended for clinical investigations, the manufacturer shall, in order to affix the CE marking, follow the procedure referred to in Annex VII and draw up the EC declaration of conformity required before placing the device on the market.

On this basis, Mucus Collector being IVD products is sold with declaration of conformity and ISO 13485:2016 certificate.

Yours sincerely,

AYSEL YILDIRIM

Quality and Regulatory Executive

Aysel YILDIRIM
Kalite ve Regülasyon Yöneticisi
Quality and Regulatory Executive

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