

EC DECLARATION OF CONFORMITY

Manufacturer

FTM AMBALAJ MEDİKAL İTH. İHR. SAN.TİC.LTD.ŞTİ.

Products

Medical Packages, Sterilization Rolls and Pouches, Sterilization Indicator Strips,
Bowie&Dick Test Packs, Adhesive Tapes.

The product above mentioned conforms the requirements of Council Directive 93/42/EEC
incl. amendment 2007/47/EC concerning medical devices. All the related documents for the
products and conformity assessment route are kept in the manufacturer's facility.

Conformity assessment route

93/42/EEC incl. amendment 2007/47/EC Annex VII

Classification

Class I Annex IX Rule 1

Standards Applied

ISO 11607-1, ISO 868-5, ISO 868-3

Place & Date of Issue

Gaziantep, June 12 2016

Manufacturer/authorized representative

Murat SAVASCI

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