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CE DECLARATION OF CONFORMITY

EU Directives covered by this Declaration

93/42/EEC MEDICAL DEVICE DIRECTIVE / 2007/47/EC

The Products Covered by this Declaration

Sterilization Tyvek Reel & Pouch

EU Representative : Neuster Medizintechnik GmbH Goethestr. 7
40237 Düsseldorf Deutschland Tax ID: 105/5832/2600

The Basis on which Conformity is being Declared

The product identified above complies with the requirements of the Medical Device Directory and its annexes above by meeting the following standard: *EN 868-5, ISO 11140-1 and ISO 11607*

The product is defined as Class 1 product and Declaration of Conformity is issued as per Annex VII of 93/42/EEC MDD.

The technical documentation required to demonstrate that the product meets the requirements of the Medical Device Directive has been compiled by the signatory below and is available for inspection by the relevant enforcement authorities.

The CE mark was first applied in May 2000

The products described above comply with the essential requirements of the directives specified.

Authority: Taner ERSEN
Date : May 2016

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ATTENTION!
The attention of the specifier, purchaser, installer, or user is drawn to special measures and limitations to use which must be observed when the product is taken into service to maintain compliance with the above directives. Details of these special methtods and limations to use are available on request.