

DECLARATION OF CONFORMITY

Manufacturer's Name: Maxtec
Address: 2305 South 1070 West
Salt Lake City, Utah 84119
USA

European Representative: QNET BV
Kantstraat 19
NL-5076 NP Haaren
The Netherlands

Product: IV Pole – Infusion Stand

Model(s): Smartstack IV Stand Family, (Includes CareFusion, SiPap Stand)

Classification & GMDN: I Stand, Infusion - 36069

Classification criteria: Clause 1.1 Rule 1 of Annex IX of MDD

We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documents are retained under the premises of the manufacturer and the European Representative.

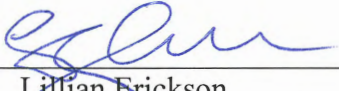
Directives: General application directives: Medical Device Directive, COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 per Annex VII as amended by 2007/47/EC of 5 September 2007

Notified Body: TÜV SÜD Product Service
RIDLERSTRASSE 65, D-80339 MUNICH, Germany
Number 0123

EC Certificate No.: Product is self-certified

Date CE mark was affixed: 20 November 2009

This declaration is considered valid from April 14, 2015 to August 31, 2017.

Signature: 
Name: Lillian Erickson
Position: Director of Regulatory and Quality

Date: 11 Apr 2017

Applied Standards

The referenced list of harmonized standards for which documented evidence of compliance can be provided includes:

EN ISO 14971:2012
ISO 15223-1:2016
ISO 13485:2012
EN ISO 10993-1:2009
EN 1041:2008