



premier O2 solutions

DECLARATION OF CONFORMITY

Manufacturer's Name: Maxtec
Address: 6526 South Cottonwood Street
Salt Lake City, Utah 84107
USA

European Representative: QNET BV
Hommerterweg 286
6436 AM Amstenrade
The Netherlands

Product: IV Pole - Infusion Stand

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

Classification and 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 II

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

EC Certificate No.: Not Applicable, Product Self Certified

Date CE mark was affixed: 20 November 2008

This declaration is considered valid from September 13, 2011 to August 31, 2014

Signature: Tammy Lavery **Date:** September 20, 2011

Name: Tammy Lavery, RAC
Position: Director of Regulatory & Quality/Maxtec Management Representative
6526 South Cottonwood Street
Salt Lake City, UT 84107
General Tel: 801-266-5300/800-748-5355 & Fax: 801-270-5590

TF0013 Rev E
Section 13