

Certificate of Compliance



No. EC.1282.0E150114.SMA0D01

Certificate's Holder:

Shenzhen Medplus Accessory Co., Ltd.
2nd floor, 2nd Building (Beside TianLiao Station),
TianLiao Village, GongMing Town, Shenzhen, China

Certification Mark:



Product:
Model(s):

Spo2 sensor&Accessory
MPS series, MPD series

Verification to:

Standard:
EN ISO 14971:2012, EN 980:2008,
EN 1041:2008, EN ISO 10993-5:2009,
EN ISO 10993-10:2010, ISO 9919:2005,
ISO 80601-2-61:2011

related to Directive(s):
93/42/EEC (Medical Devices) and subsequent
modifications and integrations

Remark: The product(s) has been verified on a voluntary basis. The product(s) satisfies the requirements of the Safety Compliance Mark of ECM, in reference to the above listed Standard(s). The above Certification Mark can be affixed on the product(s) accordingly to the ECM regulation about its release and its use.

Other relevant Standards and/or Directives have to be observed in case they are applicable.

Whereas the Manufacturer is responsible of the CE certification of the product(s) and not exempted to perform all the necessary activities before placing the product(s) on the market.

The Manufacturer is also responsible to maintain efficient the internal production control to ensure the product(s) are in compliance with the Safety Compliance Mark.

This certificate can be checked for validity at www.entecerma.org

Date of issue 14 January 2015

Expiry date 13 January 2020

Chief Manager
Tim Mahan



Deputy Manager
Vigia Miller



Ente Certificazione Macchine Srl

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