

# Certificate of Compliance



No. OP160128.SYMOT61

Technical Construction File no. TMSH1601227100

Certificate's  
Holder:

Shanghai Yuechen Medical Supply  
Co., Ltd.

8th No.776 Huhang Road, Fengxian District,  
Shanghai City, China.

Certification ECM  
Mark:



Product:  
Model(s):

Disposable Electrode  
HS01, HS02, HS03, HS04, HS05, HS06.

Verification to:

Standard:  
EN 1041:2008, EN ISO 10993-1:2009+AC:2010,  
EN ISO 10993-5:2009, EN ISO 10993-10:2013,  
EN ISO 15223-1:2012, EN ISO 14971:2012,  
EN 60601-1:2006+A1:2013

related to CE Directive(s):  
93/42/EEC including 2007/47/EC (Medical Devices)

**Remark:** The product(s) has been verified on a voluntary basis. The product(s) satisfies the requirements of the Certification 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. Regulation can be found at [www.entecerma.it](http://www.entecerma.it).

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 Certification ECM Mark.

This certificate can be checked for validity at [www.entecerma.it](http://www.entecerma.it)

Date of issue 27 January 2016

Expiry date 26 January 2021

Chief Manager  
Tim Mahan



Deputy Manager  
Viola Miller



**Ente Certificazione Macchine Srl**

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