

Certificate of Compliance



No. 1N160414.SEMUU57

Technical Construction File no. LZ201604005MDD

Certificate's
Holder:

Shanghai EMSS Med & Tech Co., Ltd.
Room 303, No. 2 Pujiang Hi-Tech Plaza, 2388
Chenhang Road, 201114 Shanghai P.R. China.

Certification ECM
Mark:



Product:

Stretcher with Strap System,
Head Immobilizer, Cervical Collar,
Spine Board with Strap System, Splint

Verification to:

Standard:
EN ISO 14971:2012, EN 1041:2008,
EN ISO 10993-1:2009/AC:2010,
EN ISO 10993-5:2009, EN ISO 10993-10:2010,
EN 980:2008

related to CE Directive(s):
93/42/EEC amended by 2007/47/EC (Medical
Devices) Annex VII
Classification: Class I, rule 1

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 Compliance Mark can be affixed on the product(s) accordingly to the ECM regulation about its release and its use. The regulation can be found at www.entecerma.it. This Certificate of Compliance can be checked for validity at www.entecerma.it

This verification doesn't imply assessment of the production of the product(s).

Additional information, clarification about the CE Marking:



We attest that a TCF for the **CE** Marking process is in place. Whereas the Manufacturer is Responsible to start the **CE Marking Certification Procedure** through an appointed Notified Body and the perform all the necessary activities, as required by the Directive and accepted by the Notified Body, before placing the **CE** Mark on the product(s).

Date of issue 14 April 2016

Expiry date 13 April 2021

Chief Manager
Tim Mahan.

Deputy Manager
Viola Miller



Ente Certificazione Macchine Srl

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