

Verification of Compliance



No. 0A130124/SEM0012

Certificate's Holder: Shanghai EMSS Med & Tech Co., Ltd.
Domestic Dept-Room 501, Oversea Dept-Room 1904,
No. 2, Lane 777, South Zhongshan 2 Road, Xuhui
District, 200032 Shanghai, P.R.C

Product: Immobilization Products
Model(s): Head Immobilizers, Cervical Collars,
Spine Boards With Strap System, Splints

Directives: 93/42/EEC Medical Devices amended by
2007/47/EC
Classification: Class I, Rule 1
Conformity Assessment Route: Annex VII

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

Remark: This Verification of Compliance has been issued on a voluntary basis. ECM confirms that a Technical Construction File (TCF) is existent for the above listed product(s). The TCF satisfactorily covers the essential requirements of the above listed Directive(s).

Other relevant Directives have to be observed in case they are applicable.

This Document is only valid for the equipment and configuration described and in conjunction with the TCF detailed above. Whereas the Manufacturer is responsible of the 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 of the internal production control to ensure the product(s) are in compliance with the essential requirements of the above mentioned Directive(s).

Date of issue JANUARY 2013

Certification Manager



Expiry date JANUARY 2018

Certification Manager



Ente Certificazione Macchine Ltd.

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