

CE Documentation Review



No. 3O190128.NFT0C21

Holder: Ningbo Fenghua Tealmed
Emergency Products Co., Ltd.
No.22 Zonyan Road, Xikou Industrial Zone,
Fenghua, Ningbo 315512, China.

Review goal: Verification of the presence of the
Technical File in regards of the Medical
Devices Directive 93/42/EEC Annex VII

Product: Splint, Stethoscope, Neurological Hammer,
Otoscope, First aid kit

Model(s): (see the following annex I)

Classification: Class I
(accordingly to the Manufacturer's declaration)

Review output: We attest that a Technical File in reference to the
Directive 93/42/EEC is in place for the CE Marking
process. Technical File identified with the no. CE/MDD-
2019(A/0) dated 2019-01-17. This document has been
issued on voluntary basis and not as NB. Whereas the
Manufacturer is responsible and not exempted to
carry out all the necessary activities, as required by the
Directive, before placing the CE Mark on the product.

Date of issue 28 January 2019

Expiry date 27 January 2024

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