



China

CE Technical Documentation Review Report

(According to MDD Directive 93/42/EEC)

Report No. TFR-SHA-59045200901

The Manufacturer

Shanghai Shenfeng Medical & Health Articles Co., Ltd.

No.159, Pengfeng Road, Malu, Jiading

201801, Shanghai P. R. China

Has Established CE Technical Documentation for the Following Products

Disposable ECG Electrode

This report is issued on a voluntary basis. It confirms that the CE technical documentation (no. QJ/SSF03CE.00, Rev A/1, Date 2020-03-24) of the listed products is complete with regard to the requirements of Annex VII section 3 of Directive 93/42/EEC. Detail products covered under the technical documentation are described in this report. This report would be re-assessed before 2020-03-31.

Issue Place:

Medical, Health Service Dept.

TÜV SÜD China, Shanghai Branch

Issue Date:

2020-03-31



Any significant changes in design or construction of the product or amendments to the directive or standards applied may render this report invalid. Also, this report is only valid in combination with ISO13485 certificate issued by TÜV SÜD.