

CE Technical Documentation Review Report

Manufacturer:

WuXi WeMade Healthcare Products Co., Ltd. No.1060, Antai 3 rd Road, Houqiao Street, Xishan District, Wuxi City, Jiangsu Province, China.

Report Number:

15093426 002

Examination intent:

Examination the completeness of the Technical Documentation according to the requirements of the Medical Devices Directive 93/42/EEC Annex VII

Product(s):

Classification:

Review result:

Type(s)/Model(s):

Bandages

Medical Bandages Width: 2.5~15cm, Length: 100~2000cm or customer specified

Cohesive Elastic Bandages Width: 2.5~15cm, Length: 100~2000cm or customer specified

Class I, rule 1 (according to manufacturer's declaration)

During the examination of the provided Technical Documentation (No.: Q/WMD-CE-01, Rev. A/1, issued on 2016-12-02), no Non-compliance according to the requirements of the Medical Devices Directive 93/42/EEC Annex VII was detected.

TÜV Rheinland (Shanghai) Co. Ltd. Quality ASS TÜVRheintz Daniel ZHU Lead Auditor, Product Assessor Medical Device Services Approv

Shanghai, 2016-12-05

Rev. 05, 2013-12-17

TÜV Rheinland (Shanghai) Co., Ltd. Unternehmensgruppe TÜV Rheinland Group

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| Manufacturer: | WuXi WeMade Healthcare Products Co., Ltd. No.1060, Antai 3 rd Road, Houqiao Street, Xishan District, Wuxi City, Jiangsu Province, China. |
|---------------------|------------------------------------------------------------------------------------------------------------------------------------------------|
| Report Number: | 15093427 002 |
| Examination intent: | Examination the completeness of the Technical Documentation according to the requirements of the Medical Devices Directive 93/42/EEC Annex VII |
| Product(s): | Sport Tapes |
| Type(s)/Model(s): | Width: 2.5~15cm, Length: 100~2000cm or customer specified |
| Classification: | Class I, rule 1 (according to manufacturer's declaration) |
| Review result: | During the examination of the provided Technical |

During the examination of the provided Technical Documentation (No.: Q/WMD-CE-02, Rev. A/1, issued on 2016-12-02), no Non-compliance according to the requirements of the Medical Devices Directive 93/42/EEC Annex VII was detected.

TÜV Rheinland (Shanghai) Gality Produ TÜVRheinland Daniel ZHU Lead Auditor, Product Assessor Approved Medical Device Services

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