

CE Technical Documentation Review Report

Applicant:

Report Number:

16807004.001

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):

Single Use Non-Woven Products:

Non-sterile Face Masks Non-sterile Caps Non-sterile Gowns Non-sterile Shoe Covers Non-sterile Isolation Gowns Non-sterile Surgical Draps

Type(s)/Model(s):

NA

Classification:

Class I

(according to manufacturer's declaration)

Examination period:

May.16.2019

Date of expiry:

May.15.2024

Review result:

During the examination of the provided Technical Documentation (No.: CE-QP-A/0, Revision: A/0, dated 2018-11-01), no Non-compliance according to the requirements of the Medical Devices Directive

93/42/EEC Annex VII was detected.

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CE Technical Documentation Review Report

Applicant:

Report Number:

50254696.001

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):

Single Use Non-Woven Products:

Non-sterile Underpads Non-sterile Sleeve Covers Non-sterile Dental Aprons Non-sterile Dental Shawls

Non-sterile Dressing Kits for Medical Use

Type(s)/Model(s):

NA

Classification:

Class I

(according to manufacturer's declaration)

Examination period:

May.16.2019

Date of expiry:

May.15.2024

Review result:

During the examination of the provided Technical Documentation (No.: CE-QP-A/0, Revision: A/0, dated 2018-11-01), no Non-compliance according to

the requirements of the Medical Devices Directive 93/42/EEC Annex VII was detected.

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CE Technical Documentation Review Report

Applicant:

Report Number:

50252775.001

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):

Single Use Non-Woven Products: Non-sterile Medical Bed Sheets Non-sterile Medical Guazes Non-sterile Surgical Gowns Non-sterile Surgical Draps Non-sterile Surgical Sets

Type(s)/Model(s):

NA

Classification:

Class I

(according to manufacturer's declaration)

Examination period:

May.16.2019

Date of expiry:

May.15.2024

Review result:

During the examination of the provided Technical Documentation (No.: CE-QP-A/0, Revision: A/0, dated 2018-11-01), no Non-compliance according to the requirements of the Medical Devices Directive

93/42/EEC Annex VII was detected.

TÜV Rheinland (China) Ltd.

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