



CE Technical Documentation Review Report

Applicant: XINLE HUABAO MEDICAL PRODUCTS CO.,LTD
Dongguan, Cheng'an Town, Xinle City, Hebei
Province,050701,China

Report Number: 16806072.001

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): Please see attachment

Type(s)/Model(s): Please see attachment

Classification: Class I
(according to manufacturer's declaration)

Examination period: Aug.18.2016

Date of expiry: Aug.17.2021

Review result: During the examination of the provided Technical
Documentation (No.: Q/HBMP06.36-2015, Revision:
A/1, dated 2015-04-20), no Non-compliance
according to the requirements of the Medical Devices
Directive 93/42/EEC Annex VII was detected.

TÜV Rheinland (China) Ltd

Chenyuhong
Yuhong CHEN
Manager
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Rev.01, 2002-10-10

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Attachment to

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Applicant: **XINLE HUABAO MEDICAL PRODUCTS CO.,LTD**
Dongguan, Cheng'an Town, Xinle City, Hebei Province,
050701,China

Product(s): **non-sterile non-woven products**
(Surgical Gowns, Surgical Drapes, Table Covers, Isolation Gowns, Coveralls, Patient Shorts, Dental Bibs, Mayo Covers, CSR Wraps, Caps, Bed Sheets, Bed Covers, Sleeve Covers, Pillow Covers, Face Masks, Examination Sheets, Shoe Covers)

non-sterile non-woven and PE composited products
(Surgical Gowns, Surgical Drapes, Table Covers, Isolation Gowns, Coveralls, Patient Shorts, Dental Bibs, Mayo Covers, CSR Wraps, Caps, Bed Sheets, Bed Covers, Sleeve Covers, Pillow Covers, Examination Sheets, Shoe Covers)

non-sterile PE products
(Surgical Gowns, Surgical Drapes, PE Gowns, Table Covers, Isolation Gowns, Coveralls, Patient Shorts, Dental Bibs, Mayo Covers, CSR Wraps, Caps, Bed Sheets, Bed Covers, Sleeve Covers, Pillow Covers, Examination Sheets, Shoe Covers)

non-sterile paper products
(Dental Bibs, Bed Sheets, Examination Sheets)

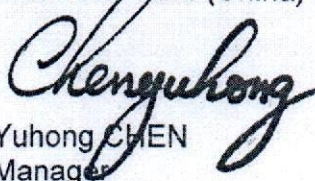
non-sterile PE and paper composited products
(Dental Bibs, Bed Sheets, Examination Sheets)

Type(s)/Model(s): Please see above

Examination period: Aug.18.2016

Date of expiry: Aug.17.2021

TÜV Rheinland (China) Ltd.


Yuhong CHEN
Manager
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