Declaration of Conformity

Manufacturer Tianchang City Anrui Medical Equipments Co., Ltd., Renhe

Industrial District, 239331 Tianchang City, Anhui Province,

People's Republic of China

European

MedPath GmbH

Representative

Mies-van-der-Rohe-Strasse8,80807 Munch, Germany

Product Name:

Latex Surgical Gloves

Specification:

6#, 6.5#, 7#, 7.5#, 8#, 8.5#, 9#

UMDNS Code:

11883

Classification (MDD, Annex IX): Ila, Rule 6
Conformity Assessment Route: Annex V.3

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Harmonised Standards. All supporting documentations are retained under the premises of the manufacturer. The manufacturer is exclusively responsible for the declaration of conformity.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC concerning medical devices (MDD 93/42/EEC).

Notified Body:

TÜV SÜD Product Service GmbH

Ridlerstr. 65, 80339 München, Germany

NB Identification number:

0123

(EC) Certificate(s):

G2 088431 0002 Rev.02

Expire date of the Certificate:

2024-05-26

Start of CE Marking:

2015-03-03

Place, Date of Issue:

Tianchang, 2020-11-04

Signature:

Name:

Biwen Zhang

Position:

General Manager

EC Declaration of Conformity AR/CE01-01(A/4)

Page 1/1