

Technical Sheet

Product: Disposable Needles SERIX 100 pcs

Manufacturer: Huaian City Hengchun

EC REP: Renault-Petersen Limited



Product Description

Advantages:

- Sterile
- Non-toxic
- Non-bacterial
- Non pyrogenic
- ISO 13485 certificated
- This is a medical device assigned to class IIa
- ANMDM approved product
- EAN available

Instructions for use

- Do not use if the package is open/damaged
- Destroy after single use
- Use within 5 years after the sterilization date

Available sizes:

- 22GX1 1/2'
- 27GX1 1/2'

Packaging: 100 pcs/box

Box size: 100 x 85 x 85



淮南市恒春医疗器材有限公司

HUAIAN CITY HENGCHUN MEDICAL PRODUCT CO.,LTD.
NO.8,YANHUANG STREET,NEW INDUSTRIAL ZONE,LIANSHUI COUNTY,HUAIAN
CITY,JIANGSU PROVINCE,223400,CHINA

TEL:+86-517-82389150/82381015,FAX:+86-517-82387747,E-mail:cileen@tymedical.sina.net

EC Declaration of Conformity

Manufacturer:

Huaian City Hengchun Medical Product Co., Ltd.
No.8, Yanhuang Styeet, New Industrial Zone,
Lianshui County,Jiangsu Province
223400, P. R. China

whose single Authorized Representative:

Caretechion GmbH
Niederrheinstr. 71
40474 Düsseldorf

We, the manufacturer, herewith declare that the products

Sterile hypodermic needles for single use

SIZE: 18G、19G、20G、21G、22G、23G、24G、25G、26G、27G。

UMDNS-Code: **12-745**

Meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class **Ila** according to Annex IX of the Directive 93/42/EEC. It bears the mark



The product concerned has been manufactured under a quality management system according to Annex V of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assured via assessment of the quality management system by the Notified Body

TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany

Certificate No.: HD 60147555 0001

Issue date: 2020-03-06

expiry date: 2024-05-26

Following the procedure relating to the EC Declaration of Conformity set out in Annex V coupled with Annex V of Directive 93/42/EEC.

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration and is only valid in connection with a batch specific Certificate of Compliance for all products concerned bearing the CE mark

The above mentioned declaration of conformity is exclusively under the responsibility of

Huaian City Hengchun Medical Product Co., Ltd.

No.8, Yanhuang Styeet, New Industrial Zone, Lianshui County,Jiangsu Province 223400, P. R. China

Lianshui China 2021-07-06

Place, date

GM: 罗成

Legally binding signature, Function

标 题: 符合性声明

文件编号: **TY/CE-001-11**



EC Certificate
Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices



Registration No.: HD 60147555 0001

Report No.: 15090199 008

Manufacturer: Huaian City Hengchun
Medical Product Co., Ltd.
No. 8, Yanhuang Street
New Industrial Zone
Lianshui County
223400 Jiangsu
P.R. China

Products: Medical Devices
(see attachment for products and site included)
Replaces Approval, Registration No.: HD 60114687 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2020-03-06

Date: 2020-03-06

Notified Body



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.



Doc. 1/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60147555 0001
Report No.: 15090199 008

Manufacturer: Huaian City Hengchun
Medical Product Co., Ltd.
No. 8, Yanhuang Street
New Industrial Zone
Lianshui County
223400 Jiangsu
P.R. China

Products:

- Infusion Sets
- Disposable Syringes
- Scalp Vein Sets
- Hypodermic Needles
- Blood Transfusion Sets
- Burette Infusion Sets for Single Use
- Sterile Blood Lancets
- I.V. Flow Regulators
- Sterile Infusion Pumps for Single Use
- Disposable Auto-destroy Syringes
- Safety-Destroy Syringes
- Disposable Safety Infusion Sets with Needle
- Syringe with O Ring Piston
- Safety Burette Infusion Sets
- Safety Burette Infusion Sets with Precision Filter

Notified Body

Date: 2020-03-06



扫描全能王 创建



扫描全能王 创建



MINISTERUL SĂNĂTĂȚII
AGENȚIA NAȚIONALĂ A MEDICAMENTULUI
ȘI A DISPOZITIVELOR MEDICALE DIN ROMÂNIA
Str. Av. Sănătescu nr. 48, sector 1, 011478 București
Tel: +4021-317.11.00
Fax: +4021-316.34.97
www.anm.ro

AVIZ DE FUNCȚIONARE
Nr. 7111 din 19.08.2020

În conformitate cu art. 926 din Legea nr. 95/2006 privind reforma în domeniul sănătății, republicată, cu modificările și completările ulterioare și în baza documentației înaintate, Agenția Națională a Medicamentului și a Dispozitivelor Medicale din România avizează funcționarea operatorului economic:

MEDPLAZA HEALTH SRL

cu sediul social și punct de lucru în sat Chiajna, comuna Chiajna, Sos Soseaua de Centura, nr 27-28, hala C2, birou nr 2, județul Ilfov

pentru activități de:

import dispozitive medicale ☐ DA ☒ NU ;

distribuție dispozitive medicale ☐ DA ☒ NU ;

instalare și/sau mentenanță dispozitive medicale ☐ DA ☒ NU

Categoriile și grupele de dispozitive medicale pentru care se execută lucrări de instalare și/sau mentenanță sunt următoarele:

Nu este cazul.

Unitatea este distribuitor/importator al producătorilor:

Nume producator	Tara
HUIAN CITY HENGCHUN MEDICAL PRODUCT CO.LTD	CHINA

Nume producator	Tara
HUIAN CITY HENGCHUN MEDICAL PRODUCT CO.LTD	CHINA

Unitatea este reprezentant autorizat în Uniunea Europeană al producătorului:

Nu este cazul.

Orice modificare a condițiilor stabilite prin reglementările Agenției Naționale a Medicamentului și a Dispozitivelor Medicale din România care au stat la baza avizării atrage anularea prezentului aviz de funcționare.

Avizare inițială la data **19.08.2020**

Valabil până la **18.08.2023**

PREȘEDINTE

Bujor Eugen ALMĂȘAN



Thank you!



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