



EU DECLARATION OF CONFORMITY

Manufacturer:

Crown Name Disposable Hygiene Products Fty. Ltd.

No.508 Qi'an Avenue, Zhucheng Street, Xinzhou District, Wuhan City, Hubei Province, P. R. China

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Email: technicalsupport@crowname.com

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Authorized Representative:

Lotus NL B.V.

Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

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Email: peter@lotusnl.com

We, the manufacturer, hereby declare that the medical devices covered by the present declaration, are in conformity with Medical Device Regulation (EU) 2017/745.

Product Model	Isolation Gown (Non-sterile)
EMDN code and description	T0205 - NON-SURGICAL GOWNS (EXCLUDING PERSONAL PROTECTIVE EQUIPMENT - PPE)
Basic UDI-DI	697312251IG10073
Classification and Rule	Class I, Rule 1 according to Annex VIII of Regulation (EU) 2017/745
Conformity Assessment Route	Article 19, Annex II and Annex III according to Regulation (EU) 2017/745

This Declaration of Conformity is issued under the sole responsibility of the manufacturer.

Signed for on behalf of Crown Name Disposable Hygiene Products Fty. Ltd.

Name of Authorized Person: Dongfang Xu



Title: Management Representative

Date: 2022/02/16

Place: Hubei, China



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Model Number (REF)	Product Name
CN307	Disposable PP Isolation Gown
CN308	Disposable PP/PE Isolation Gown
CN309	Disposable SMS, SMMS Isolation Gown
CN313	Disposable SMS Gown
CN314	Disposable SMS, SMMS Isolation Gown with Short Sleeve
CN319	Disposable SMS/PE Isolation Gown
CN320	Disposable Isolation Gown, PP/PE in front and sleeves, PP at back

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ANNEX

Crown Name's Model Number	ENERRE PHARMA's Model Number	Product Name
CN308	CN3085335	Disposable PP/PE Isolation Gown