

DECLARATION OF CONFORMITY

Product Identification		
Product name	Type	Brand
Sterile Surgical Gown SMMMS	Standard	OPERO
Sterile Surgical Gown SMMMS	Reinforced	OPERO
Manufacturer		
Name of company	Address	Representative
Crown Name Disposable Hygiene Products Fty., Ltd.	ChengBei Village Zhu Cheng Street XinZhou District, Wuhan City Hubei Province, China	Cynthia Ye

Authorized Representative in UE		
Name of company	Address	Phone
Lotus Global Co., Ltd.	1 Four Seasons Terrace West Drayton, Middlesex London, UB7 9GG United Kingdom	-

Conformity Assessment	
Device classification	Compliance
Class I according to Annex IX of MDD 93/42/EEC	Council Directive 93/42/EEC amended by Directive 2007/47/EC

The manufacturer declares that the above mentioned product meet the provision of the European Council Directive 93/42/EEC (including the last amendment from 2007) and conform to the following standard: MDD 93/42, EN 13795:2011 + A1:2013, EN ISO 11135:2014, EN 556-1|AC:2006.

Company Representative:

Name: Cynthia Ye

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