

Declaration of Conformity

For the following products:

Disposable Skin Markers Class 1s

(Product Name)

663021、663022、663121、663122

(Model Designation)

is hereinafter confirmed to comply with the requirements set out in the Council Directive on the harmonization of the Laws of the Member States concerning Medical Device Directive (93/42/EEC As amended by 2007/47/EC)

Applicable harmonized standards are:

MEDDEV 2.12-1, MEDDEV2.7.1, EN ISO13485:2016, EN ISO 14971:2012,
EN ISO14155:2011, EN ISO 10993-1:2009, EN ISO 10993-5:2009, EN ISO 10993-10:2009 ,
EN ISO 11607-1:2009, EN ISO11607-2:2006, EN ISO 11737-1:2006, EN ISO 11737-2:2009,
ISO 14644 -1:2010, ISO 14644-2:2000, IEC 62366:2008, ISO15223-1:2016

Conformity Assessment Route:

Annex V of Medical Device Directive

Notified Body:

DNV GL Presafe AS (NB No. 2460)
Veritasveien 3, 1363 Høvik, Norway
EC certificate No. 10000319830-PA-NA-CHN Rev.1.0

The following European Authorized Representative is stated to the declaration:

Company Name: MDI EUROPA GMBH

Company Address: Langenhagener Str. 71, D-30855 Langenhagen, Germany

The following manufacturer is exclusively responsible for making this declaration:

Company Name: Dong Guan Concord Medical Products Ltd.

Company Address: 4thFloor Block C, Yue Neng Industrial Park, Xia Bian Village,
Hou Jie, Dong Guan, China



(Legal Signature)

Managing Director

(Position/title)

22/4/2022

(Date)