Declaration of Conformity

For the following products:

Medical Sodium Hvaluronate Gel

(Product Name)
Medical Sodium Hvaluronate Gel for Bone Joint

Brand Name	Model Designation	Classification
Quickclean®, SingJoint®	l0mg/ml: 1.0m1, 2.0m1, 2.5m1 12mg/ml: 1.0m1, 2.0m1, 2.5m1 20mg/ml: 2.0m1, 3.0ml	**III**
JOINT MD® EXPRESS	10mg/m1: 2.0m1	**III**
Arthro One™	20mg/ml: 2.0m1, 3.0ml	**III**

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:

EN ISO14971:2019
EN ISO13485:20167/AC:2016
EN ISO15223-1:2016
EN ISO10993-3:2014
EN ISO10993-11.-2018
EN 62366-1:2015
EN ISO11607-1: 2009
EN 556-1. 2001/AC:2006
EN ISO11607-2:2006
EN ISO10993-5:2009
EN ISO14644-1:2015
EN ISO17665-1:2006
EN 1041:2008
EN ISO10993-1:2009/AC:2010
EN ISO10993-6:2009
EN ISO11138-3:2009

Conformity Assessment Route:
Annex II including section 4 of Medical Device Directive

Notified Body:
DNV Product Assurance AS (NB No. 2460)
Veritasveien 3, 1363 Høvik, Norway

The following European Authorized Representative is stated to the declaration:
Company Name: Hangzhou Singclean Medical Products Filial Sweden
Company Address: Norra Rosenbergsgatan 2A
42676 VÄSTRA FRÖLUNDA, Sweden

The following manufacturer is exclusively responsible for making this declaration:
Company Name: Hangzhou Singclean Medical Products Co., Ltd.
Company Address: No. 125 (E), l0th Street, Hangzhou Economic and Technological Development Zone, Zhejiang, China 310018

(Legal Signature)	Weiqing Sun General Manager (Name/Position)	2021. 03. 05 (Date)