



EU Declaration of Conformity

Ningbo Five Continents Medical Instrument Co., Ltd.

No. 63-9, Modao Bridge Road, Yuyao, Zhejiang Province 315400,
China

CN-MF-000009685

AUTHORIZED REPRESENTATIVE
(name and address):

Caretechion GmbH
Niederrheinstraße, 71 40474 Düsseldorf, Germany

PRODUCTS:

Product Name	Product number / catalogue number	Basic UDI-DI	Description	Classification
Disposable Surgical Lavage System	See appendix 1	69413857200001VS	Disposable Surgical Lavage System is used to irrigate, wash, and evacuate debris from general soft-tissue and orthopedic surgical sites (soft-tissue wound or bone debridement, site cleaning, bone cement residue removal) with a pulse jet of sterile fluid (saline). The device is provided with sterile, and for single use only.	Class IIa;

CONFORMITY ASSESSMENT ROUTE: Directive 93/42/EEC Annex II, excluding Section 4

We herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 93/42/EEC for medical devices. All supporting documentation is retained at the premises of the manufacturer.

STANDARDS APPLIED:

Applied standards are listed in the General Safety and Performance Requirements Checklist

NOTIFIED BODY:

TÜV Rheinland LGA Products GmbH
Tillystraße 2
90431 Nürnberg
Deutschland
The Netherlands
Notified body number: **0197**

EU CERTIFICATE:

HD 60145145 0001

EU TECHNICAL DOCUMENTATION
ASSESSMENT CERTIFICATE:

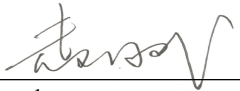
N/A

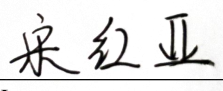
START OF CE MARKING:

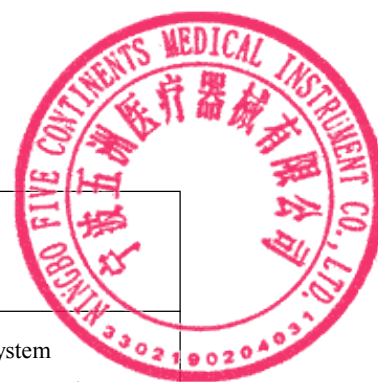
Product Name	Product Number	Date of First CE Marking	First Batch Manufactured under Current Notified Body Number
Disposable Surgical Lavage System	See attached form	2011/06/06	/

Place, Date of issue: Yuyao, 01.28.2022

SIGNATURE:


Zhao Guozhen
General Manager
For and on behalf of Ningbo Five Continents Medical Instrument Co., Ltd.


Song Hongya
Regulatory Affairs Supervisor
For and on behalf of Ningbo Five Continents Medical Instrument Co., Ltd.



Model	Type	Product name
External battery type	WZ-WDS-01	Disposable Surgical Lavage System
	WZ-WDS-02	Disposable Surgical Lavage System
	WZ-WDS-03	Disposable Surgical Lavage System
	WZ-WDS-04	Disposable Surgical Lavage System
	WZ-WDS-05	Disposable Surgical Lavage System
	WZ-WDS-06	Disposable Surgical Lavage System
	WZ-WDS-07	Disposable Surgical Lavage System
Internal battery type	WZ-WPL-01/ MPPL01/ FNM2010400	Disposable Surgical Lavage System
	WZ-WPL-02/ MPPL06	Disposable Surgical Lavage System
	WZ-WPL-03/ MPPL04	Disposable Surgical Lavage System
	WZ-WPL-04/ MPPL05	Disposable Surgical Lavage System
	WZ-WPL-05/ MPPL02	Disposable Surgical Lavage System
	WZ-WPL-06/ MPPL07	Disposable Surgical Lavage System
	WZ-WPL-07/ MPPL03	Disposable Surgical Lavage System
/	WZ-PT-01	Short tip
/	WZ-PT-02	Long tip
/	WZ-PT-03/MPPLFB	Femoral brush tip
/	WZ-SH-01	Splash shield.