

**DECLARATION OF CONFORMITY
HUNAN ZHENHEYIKANG MEDICAL INSTRUMENT CO.,LTD**

We, [HUNAN ZHENHEYIKANG MEDICAL INSTRUMENT CO.,LTD], as the [Product Owner], hereby declare that the below mentioned devices have been classified according to the classification rules and conform to the Essential Principles for Safety and Performance as laid out in the ASEAN Agreement on Medical Device Directive.

Name and Address of Product Owner:

HUNAN ZHENHEYIKANG MEDICAL INSTRUMENT CO.,LTD
NO.6 Building Jingxiang Energy, No.55 Xiaguang east road,Gaoxin district Xiangtan, Hunan

Name and Address of Physical Manufacturer:

HUNAN ZHENHEYIKANG MEDICAL INSTRUMENT CO.,LTD
NO.6 Building Jingxiang Energy, No.55 Xiaguang east road,Gaoxin district Xiangtan, Hunan

Name and Address of Authorized Representative:

██████████

Work place 1 No. 8/122 ratchada-ramintha Road, ramintha, kannayaw district , bangkok 10230>

Medical Device(s):

< Durgesh Disposable basic dressing set
Model Number ZK11010520 >

Risk Classification: e.g. Class A, rule

< Class 1 Rule 1 >

Quality Management System Certificate:

ISO13485:2016

Certification Body :HUNAN ZHENHEYIKANG MEDICAL INSTRUMENT CO.,LTD

Certificate Number:211100B0/007005

issue date: feb.02,2021.

expiry date:Sep.17,2023

Standards Applied:

ISO13485:2016

This declaration of conformity is valid from 11 July,2023

Authorized Signatory

Viva
Viva Rong, General Manager



7.11.2023