DECLARATION OF CONFORMITY

MANUFACTURER: DANYANG SUNMED HEALTHCARE CORPORATION
ADDR: NO. 3, BEI ER HUAN, DANYANG CITY, JIANGSU PROVINCE, CHINA
SRN: CN-MF-000013734

EUROPEAN REPRESENTATIVE: EC REP SHANGHAI INTERNATIONAL HOLDING CORP. GMBH (EUROPE)
ADDR: EIFFESTRASSE 80 D-20537 HAMBURG, GERMANY
SRN: DE-AR-000000001

WE DECLARE UNDER OUR SOLE RESPONSIBILITY THAT

NAME OF MEDICAL DEVICE: ISOTHERMIC BAG
EMDN CODE:
TYPE:
PRODUCT CODE:
INTENDED USE: PROVIDE ISOTHERMIC PROTECTION AGAINST HOT AND COLD TEMPERATURES.
BASIC UDI-DI:

OF CLASS: CLASS I
ACCORDING TO ANNEX VIII OF REGULATION EU 2017/745(MDR)

HARMONISED STANDARDS:EN ISO 13485:2016; EN 14971:2019; EN 1041:2008; EN 15223-1:2021;
CS REFERENCE:

CONFORMITY ASSESSMENT PROCEDURE:THE TECHNICAL DOCUMENTATION REGARDING THE DEVICE THAT IS COVERED BY THIS DECLARATION COMPLIES WITH ANNEX II & III

CONFORMITY STATEMENT: THE DEVICE COVERED BY THIS DECLARATION IS IN CONFORMITY WITH REGULATION 2017/745 (MDR) (AND IF APPLICABLE, WITH ANY OTHER RELEVANT UNION LEGISLATION THAT PROVIDES FOR THE ISSUING OF AN EU DECLARATION OF CONFORMITY)

NOTIFIED BODY: TÜV PRODUCT SERVICE GMBH
RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY

IDENTIFICATION NUMBER CE

(EC) CERTIFICATE(S): Q6 060669 0021 REV. 03

PLACE, DATE OF ISSUE: DANYANG, 26 FEB 2025
SIGNATURE: SUN WEI LIANG
NAME
POSITION (GENERAL MANAGER)

丹阳市尚美医材有限公司
DANYANG SUNMED HEALTHCARE CORPORATION