Declaration of Conformity

The manufacturer of the products covered by this Declaration is Anji Hengfeng Sanitary Material Co., Ltd. Ancheng, Dipu Town 313300 Anji County, Zhejiang China.
The product is exclusively distributed by H&H Medical Corporation, 328 McLaws Circle Williamsburg, Virginia USA 23185. Authorized representative established in the community is SUNGO Europe B.V. Olympisch Stadion 24 1076DE Amsterdam.

The Directives Covered by this Declaration

Directive 93/42/EEC of the European Communities and of the council of 14 June 1993 concerning medical devices.

The Products Covered by this Declaration

H&H Compressed Gauze
Compressed roll of crinkle fluff gauze of **Class Is** for blood loss NSN 6510-01-503-2117.

complies with provision of the EC Directive 93/42/EEC as amended by EC Directive 2007/47/EC which apply to it based on its intended use under the supervision of TŰV Rheinland LGA Products GmbH, a Notified Body duly authorized by EU Competent Authority to carry out such assessments and carrying the Notified Body number 0197

Certification of a quality system according to:

Directive **93/42/EEC, Annex V** (excluding Section 4) and amending directive 2007/47/EC - Certificate Number: **DD 60137855 0001**

EN ISO 13485:2016 - Certificate Number: **SX60137856 0001**

List of Technical Standards, Specifications, and Harmonized Norms used for Review of its Conformity

ISO 9001 :2008 Quality management system Requirements
EN ISO 13485;2016 Medical devices Quality management systems- Requirements for regulatory purposes (ISO 13485 2016)
EN ISO 15223-1:2016 General Requirements. Symbols to be used with medical device labels, labelling and information to be supplied.
EN ISO 10993-7:2008 Biological Evaluation of medical devices Part 7: Ethylene Oxide sterilization residuals (ISO 10993-7:2008)
EN ISO 10993-10:2010 Tests for irritation and sensitization
EN ISO 10993-12:2012 Sample Preparation
EN ISO 10993-22006 Animal Welfare
EN ISO 10993-5:2009 Biological evaluation of medical devices Part 5: Tests for in vitro cytoxicity (ISO 109935:2009) ANSI/AAMI/ISO 1 1 137-2:2013 Sterilization of Healthcare Products Radiation Establishing Radiation dose —Method VDmax.
ANSI/AAMVISO I i 1371 :2006/(R) 2010 Sterilization of Healthcare Products Radiation Part I : Requirements for development, validation, and routine control of a sterilization process for medical devices.

ANSI/AAMI/ISO I i 737-1) 2011 Sterilization of medical devices Microbiological methods Part I : Estimation of Populatoin of microorganisms on products

ISO 1 1737-2:2009: Sterilization of Medical Devices Microbiological methods Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process.

EN ISO 1 1 137-1:2015 Sterilization of health care products. Radiation Requirements for development, validation and routine control of a sterilization process for medical devices.

EN ISO 11137-2:2015 Sterilization of health care products Radiation Part 2: Establishing the sterilization dose USP/NF, U S. Pharmocopeia <71> (current version)

USP 40/ NF 35 United States Pharmacopeia/National Formulary 2017

AAMI TIR 33:2005 Sterilization of health care products - Radiation Substantiation of selected sterilization dose AAMI TIR 35:2016 Sterilization of health care products - Radiation sterilization alternative sampling plans for verification dose experiments and sterilization dose audits

AAMI TIR 40:2009 Sterilization of health care products -- Radiation Guidance on dose setting utilizing a modified method 2

EN ISO 14971 : 2012 Medical Devices Application of risk management to medical devices (ISO 14971 :2007)

EN ISO 1 1607-1 :2009+Al :2014 Packing for terminally sterilized medical devices Requirements for materials, sterile barrier systems, and packaging systems.

The Basis on which Conformity is being Declared

The manufacturer hereby declares under his sole responsibility that the product identified above complies with the protection requirements of the Directive and with the principal elements of the above standards applied.

The technical documentation required to demonstrate that the product meets the requirements of the directive has been compiled and is available for inspection by the relevant enforcement authorities. The CE mark was first applied in 2019. This certificate will remain valid until approved design change, but until March 23,2024 at the latest.

Signature: Maggie

Titile: Sales Manager

Stamp: 安吉恒丰卫生材料有限公司 ANJI HENGFENG SANITARY MATERIAL CO.,LTD

Date: Dec 17th, 2021