桂林市啄木鸟医疗器械有限公司
GUILIN WOODPECKER Medical Instrument Co.,LTD.

File No.: ZMN-YF-AW1-01-001-008
Version: A

EC Declaration of Conformity

Manufacture	**Guilin Woodpecker Medical Instrument Co.,Ltd** Information Industrial Park, Guilin National High-Tech Zone, Guilin, Guangxi, 541004 P.R. China SRN:CN-MF-000009139
European Representative:	**MedNet EC-Rep GmbH** **Borkstrasse 10·48163 Muenster Germany** SRN:DE-AR-000000002
Product Name: **Model**	**Prophylaxis Powder** **PT-S1, PT-S2, PT-S3**
Brands:	

Classification (MDR, Annex VIII): Class I / Rule 1, (MDR, Annex VIII)
GMDN Code: 45407
UMDNS Code: 16699
Basic UDI - DI: 694484369021LV
SRN: CN-MF-000009139
Conformity Assessment Route: Annex II, Annex III of (EU)2017/745, MDR

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Regulations and Standards. All supporting documentations are retained under the premises of the manufacturer. We, the manufacturer, are exclusively responsible for the Declaration of Conformity.

General applicable regulations: Medical Device Regulation, (EU)2017/745.

Standard	EN ISO 14971:2019, EN ISO 15223-1:2016, EN 1041：2008+A1:2013, EN ISO 10993-1:2009, EN ISO 10993-5:2009, EN ISO 10993-10:2013, EN 61025:2007, 2011/65/EU (ROHS 2.0), EN ISO 20608-2018, EN ISO 7405：2018, EN 62366：2008, EN ISO 13485:2016, MEDDEV 2.7/1 Rev.4, MEDDEV 2.12/2 Rev.2

Place, Date of Issue

Name: 宁加康 (Ning Jiakang)

Position: PRRC

Location: Guilin, China

Signature: 2021.12.22