

EU DECLARATION OF CONFORMITY

According to Art. 19 of Regulation (EU) 2017/745 on Medical Devices

Manufacturer: Zhejiang Ailebao Medical Technology Co.,Ltd.
2nd Floor, No.192 Xingxian Road, Longgang City,
Wenzhou City, Zhejiang Province, China, 325802.

Trademark: Ailebao

SRN: Not available yet

European Representative: MedPath GmbH
Mies-van-der-Rohe-Strasse 8
80807 Munich, Germany

SRN: Not available yet

Trade name: Ostomy Collection Bags

Product name: Ostomy Collection Bags

Product code / Catalogue number: A2O3260 series; A2C3160 series; A1C1160 series;
A1O2260 series; A2U6260 series; A1U5160 series.

Basic UDI: Not available yet

Classification acc. to MDR Ax. VIII: Class 1, rule 1

Applied Standard & Common Specification: EN ISO10993-1:2009; EN ISO10993-5: 2009;
EN ISO10993-10:2010; EN ISO 14971: 2012

Conformity assessment procedure: Annex II + Annex III of MDR;

CE certificate No.: N.A.

Name and ID of the Notified Body: N.A.

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR). All supporting documentations are retained under the premises of the manufacturer.

Sheng Chunsheng,
General Manager

Longgang, 04. 11. 2020