



# NINGBO HI-TECH UNICMED IMP. & EXP. CO., LTD

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## EU Declaration of Conformity

### Manufacturer:

Name: Ningbo Hi-Tech Unimed Imp. & Exp. Co., Ltd.  
Add: 11/F, Green Town Lvyuan Tower, No.588 Canghai Road,  
Ningbo, China

### European Representative:

Name: Shanghai International Holding Corp. GmbH(Europe)  
Add: Eiffestrasse 80.20537 Hamburg, Germany

**Product Name:** PE Apron

**Trade name /Trademark:** N.A.

**Model:** LDPE

**SRN:** Not yet

**GMDN Code:** 40503

**Basic UDI-DI:** 6974495690104013C

**Classification (MDR, Annex VIII):** I, rule 1

**Conformity Assessment Route:** Annex VIII

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.

## REGULATIONS

### General applicable regulations:

Medical Device Regulation: REGULATION (EU) 2017/745

**Place of Issue:** Ningbo, CHINA

**Date of Issue:** 2021-06-09

**Signature:** Mr. Honghao Zhou

**Position:** General Manager

