



# EC DECLARATION OF CONFORMITY

**Manufacturer:**

Name: MULTIBRANDS  
INTERNATIONAL LTD  
Address: Royds Hall, Royds Hall Lane,  
Bradford, England BD12 0EJ

**Whose Authorized Representative:**

Name: Lotus NL B.V.  
Address: Koningin Julianaplein 10,1e Verd,  
2595AA, The Hague, Netherlands.  
E-mail: peter@lotusnl.com

We, the manufacturer, herewith declare that the products

<b>Name</b>	Panodyne Disposable Medical LDPE APRON(non-sterile)	<b>Model</b>	70*120cm, 70*135cm
<b>Intended Use</b>	The raw material of this product is LDPE, which has isolation effect on virus aerosol, virus-containing liquid, etc. When this product is taken off, the outer surface of the apron is not in contact with the human body.	<b>Classification</b>	I, (MDR, Annex VIII rule 1)

meet the provisions of the Medical Device Regulation (MDR) 2017/745 which apply to them.

**Conformity Assessment Route:** Annex II and Annex III and Article 19 according to MDR 2017/745.

**Applicable Standards:**

EN 1041:2008	Information supplied by the manufacturer with medical devices
EN ISO15223-1:2016	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied Part 1: General requirements
ISO 10993-1: 2018	Biological evaluation of medical devices — Part 1: Evaluation and testing
EN ISO 10993-5: 2009	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2010	Biological evaluation of medical devices — Part 10: Tests for irritation and delayed-type hypersensitivity
EN 62336-1:2015	Medical devices Application of usability engineering to medical devices
BS EN 13795-1:2019	Surgical clothing and drapes - Requirements and test methods

We, the manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL(MDR). We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on: 17/06/2020

Name of authorized signatory:  RIDWANA HUSAIN

Place: Bradford, England

Position held in the company: General Manager

MULTIBRANDS INTERNATIONAL LTD