



EU Declaration of Conformity

Manufacturer:

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Authorised Importer & Distributor:

Leli Group Holding B.V.
Curieweg 15
2408 BZ Alphen aan den Rijn
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The Manufacturer declares under full responsibility that the following **Medical Device Class 1** products are in conformity with the provisions of the Medical Device Regulation (EU) 2017/745:

Brand Name	Product	Product Code	Colour	European Standard	Classification
Banitore, Hearttex, Hengan	Disposable Surgical Mask (earloops)	XCJ010-I	White	EN 14683:2019+AC:2019	Type I
Banitore, Hearttex, Hengan	Disposable Surgical Mask (earloops)	XCJ010-II	White	EN 14683:2019+AC:2019	Type II
Banitore, Hearttex, Hengan	Disposable Surgical Mask (earloops)	XCJ010-IIR	White	EN 14683:2019+AC:2019	Type IIR
Banitore, Hearttex, Hengan	Disposable Surgical Mask (soft earloops)	XCW010-I	White	EN 14683:2019+AC:2019	Type I
Banitore, Hearttex, Hengan	Disposable Surgical Mask (soft earloops)	XCW010-II	White	EN 14683:2019+AC:2019	Type II
Banitore, Hearttex, Hengan	Disposable Surgical Mask (soft earloops)	XCW010-IIR	White	EN 14683:2019+AC:2019	Type IIR

In accordance with the Medical Device Regulation (EU) 2017/745 Annex I, §23 the packaging of the products will bear the number of the European Standard, Classification (Type of Mask) and CE-marking before being placed on the consumer market by the Importer.



1 July 2020

Mr. Martin Li, Chief Financial Officer
Hengan International Group Company

