

EU Declaration of Conformity

Manufacturer: Hunan Cofee Medical Equipment Co., Ltd
Jinlong Industrial Park, Furong North Road, Xiangyin County,
Yueyang City, Hunan Province, China

SRN: /

European Representative: Riomavix Sociedad Limitada
Calle de Almansa 55, 1D, Madrid 28039 Spain

SRN: ES-AR-000001202

Product Name: Crutches (Axillary Crutches/ Elbow Crutches/
Folding Canes/Quad canes)

GMDN Code: 31115/31113

UDI-DI: 697152482GZLSV

Classification (MDR, Annex VIII): Class I, Rule 1.

Conformity Assessment Route: EU DECLARATION OF CONFORMITY
following the Annex II + Annex III + Article 19 of MDR (EU) 2017/745.

We herewith declare that the above mentioned products meet the
transposition into national law, the provisions of the following EU Regulation
and Standards. All supporting documentations are retained under the
premises of the manufacturer.

The manufacturer is exclusively responsible for the declaration of
conformity.

General applicable regulations, directives:

Regulation (EU) 2017/745 of the European Parliament and of the Council of
5 April 2017 on medical devices, amending Directive 2001/83/EC,
Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and
repealing Council Directives 90/385/EEC and 93/42/EEC.

Applied standards, common specification, guidance:

EN ISO 15223-1:2016, EN 1041:2008+A1:2013, EN ISO 14971:2012, EN
62366-1:2015+AC:2015, ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-
10:2010, MDCG 2019-15.

Signature:

Name:

Position:

Place/date:



General Manager
China, July 2, 2021

