

Jiangxi Rainbow Medical Products CO.,LTD

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EU DECLARATION OF CONFORMITY

Doc No:LB/CE-01

Identification of the Legal Manufacturer & Address		: Jiangxi Rainbow Medical Products Co.,Ltd : East side of Jianshe Road,Penghuwan Area,Jiujiang City, Jiangxi Province,China
European Authorized Representative		: CMC Medical Devices&Drugs,S.L. : C/Horacio Lengo N.18,CP 29006,Malaga-Spain : Tel: +34 951387714
Basic UDI-DI		: 697429063C50P7
Product & Identification		: Vinyl Examination Gloves for Single Use
Intended purpose of the product		: Examination Gloves for Single Use are disposable gloves used during medical examinations to help prevent cross-contamination between operator and patients.
GMDN code and product		: 47176 Vinyl examination/treatment glove,non-powdered : 47177 Vinyl examination/treatment glove,powdered
Risk Classification		: Class 1 ,Non Sterile,no measuring function and not surgical instrument

We hereby declare that the above mentioned devices comply with the European Medical Device Regulations (EU)MDR 2017/745.The EU declartion of conformity is issued under the sole responsibility of the manufacturer.

Conformity Assessment Procedure	: Annex VIII,Rule 1
Conformity Route	: Self-Declaration
Relevant Harmonized Standards	: EN ISO13485:2016 : EN455-1:2000,EN455-2:2015,EN455-3:2015,EN455-4:2009 : EN ISO 374-1:2016,EN374-2:2014,EN16523-1:2015,EN374-4:2013, EN ISO 374-5:2016,EN ISO 21420:2020
Quality System Certificate	: Certificate No: Q6 105935 0001 Rev.00 : Certificate Body:TUV SUD Product Service GmbH
Identification of the person Authorized to sign on behalf of The Legal Manufacturer	: Signed by : 
	:Date :22.06.2020