


EU DECLARATION OF CONFORMITY

Doc No:LB/CE-01

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| 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 | | : Details please reference the Article 2.11. of the CE technical files |
| 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.

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| 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,EN420:2003+A1:2009 |
| 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 |