DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

MedNet EC-Rep GmbH
Borkstrasse 10, 48163 Münster, Germany

Manufacturer

Name: RELYNC TECH LTD.

Address:

5B01,11 Building,The capital of the design,TianMian Village,HuaFu Str, FuTian District,ShenZhen City,GuangDong Province,China

Conformity Assessment

Conformity Assessment Procedure

Annex II+III of Regulation (EU) 2017/745

Applied Standards

EN12184:2014
EN ISO 14971: 2019
EN ISO 15223-1: 2016
EN 1041:2008+A1:2013
Meddev 2.7/1 Rev4
Meddev 2.12/1 Rev8
ISO 13485:2016

Remark

The declaration of conformity is valid in connection with the release technical document CE-MDR-TCF01.

All the supporting documentation is retained at the premises of the manufacturer.

The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.

Product Information

Name : Mobility scooter
Model : RAA
Trade name: Relync R1
Basic UDI-DI : 69721189800
Classification: Class I, According to Rule 1, Annex VIII, Regulation (EU) 2017/745

Declaration

We, the manufacturer herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Signature: Date: 20210401

Position: GM Place: Shenzhen, China