

UK Declaration of Conformity

According to the **Medical Devices Regulations 2002**

Manufacturer:

Xiamen World Gear Sports Goods Co., Ltd

Address:

No.27-29 North 2nd Road, Xinglin, Jimei District Xiamen,361022,
China

We hereby declare under our sole responsibility that the device specified is in conformity with the Medical Devices Regulations 2002 (SI 2002 No 618) as amended by the Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (SI 2020 No. 1478)

UK Responsible Person:

Share Info Ltd.

Address:

3rd Floor, Office C, Townend House, Park Street, Walsall,
West Midlands,WS1 1NS, United Kingdom

Product Name:

Rise Sit to Stand

Model:

PR51STSP

Risk class:

Class I as defined by rule 12 of Annex IX of EU directive 93/42/EEC – as defined by UK regulation SI 2002 No 618, Part 2, regulation 7

Conformity assessment procedure:

Annex VII of Directive 93/42/EEC – as defined by UK regulation SI 2002 No 618, Part 2, regulation 13

Basic UDI-DI:

697451201PR51STSPZQ

Applied Standard(s):

EN ISO 13485:2016

EN 12182:2012

EN ISO 14971:2019

EN ISO 10535: 2006

EN 1041:2008

EN 60601-1:2006 + A1 :2013

EN 62366-1:2015

EN 60601-1-2: 2015

EN ISO 15223-1:2021

IEC 60601-1-6:2010

EN ISO 10993-5:2009

IEC 60601-1-11:2015

EN ISO 10993-10:2010



General manager: Jim Wu

Place: Xiamen, Fujian, China

Date: 13/04/2022

