

EU Declaration of Conformity

According to Art. 19 of Regulation (EU) 2017/745 on Medical Devices

Name: Shanghai Greejoy Industry Co., Ltd.
Manufacturer: Add: 6 Building, Songhuang Road 999, Qingpu District, 201706. Shanghai, China
SRN: CN-MF-000035370
European Name: Prolinx GmbH
Representative: Add: Brehmstr. 56, 40239, Duesseldorf , Germany
SRN: DE-AR-000005129
Product Name: Medical Oil Free Air Compressor
Trade Name: /
Basic UDI-DI : 697654080GA2Y
Product Models: GA-61 GA-81 GA-62 GA-82 GA-63 GA-83
GA-64 GA-84
Classification acc. to MDR Ax. VIII: Class I, Rule13
Conformity assessment procedure: Regulation (EU) 2017/745 Annex XI Part A
Applied Common Specification/ standard: EN ISO 13485:2016 EN ISO 15223-1:2021 EN ISO 14971:2019/A11:2021
EN ISO 20417:2021 IEC 60601-1:2005 +A1:2012+A2:2020
IEC 60601-1-2:2014+A1:2020 EN 62366-1: 2015+A1:2020
IEC60601-1-6: 2010+A1: 2013+A2: 2020

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR), any other relevant Union legislation that provides for the issuing of an EU declaration of conformity, any CS used and in relation to which conformity is declared and other relevant regulations. All supporting documentations are retained under the premises of the manufacturer.

Place of Issue: Shanghai, China
Date of Issue: July 25, 2024
Signature:

Name: Mr.Mingbao Lu
Position: General Manager

