EC Declaration of Conformity

Manufacturer:

Beijing KellyMed Co., Ltd.
Room 115,4# Building, No.2 Tiyuan West Road, Haidian District, Beijing, 100084, China

whose single Authorized Representative:

Umedwings Netherlands B.V.
Radonstraat 28,2718TA
Zoetermeer,The Netherlands
Tel: +31(0)642758955
E-mail:ar@umedwings.eu

We, the manufacturer, herewith declare that the products

Syringe pump
Model: KL-602,KL-702,KL-605T,KL-6061N
*(*including system components and accessories*)*
GMDN Code: 13217

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class IIb according to Annex IX of the Directive 93/42/EEC. It bears the mark

CE 1639

The product concerned has been designed and manufactured under a quality management system according to Annex II (excluding Section 4) of Directive 93/42/EEC.

General applicable directives:
Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC). Amended by DIRECTIVE 2007/47/EC of 5 September 2007

Standard Applied:

EN ISO 15223-1:2016	EN 1041:2008	EN ISO 14971:2012
EN ISO 14155:2011	IEC 60601-1:2005	EN 60601-1-2:2015
EN 60601-1-6:2010	IEC 60601-1-8:2006	IEC 60601-2-24:2012
EN 62304:2015	EN 62366-1:2015	EN 10993-1:2009
IEC/TR 60878-2015	MEDDEV 2.7/1 revision 4	MEDDEV 2.12/2 Rev2
MEDDEV 2.12-1 Rev8		

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

SGS Belgium NV
SGS House Noorderlaan 87 2030 Antwerp Belgium

Certificate No.: CN19/41114
Issue date: 22 September 2020
Expiry date: 24 May 2024

following the procedure relating to the EC Declaration of Conformity set out in Annex II (excluding Section 4) of Directive 93/42/EEC.

The above mentioned declaration of conformity is exclusively under the responsibility of

Beijing KellyMed Co., Ltd.

Beijing, November. 04,2021

Place , date

Legally binding signature, Function