Certificate KR11/01629

The management system of

MIKA MEDICAL CO.

93, Noksansaneopjung-ro, Gangseo-gu, Busan, Republic of Korea

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

Design, Development and manufacture of Needle free injection system for the subcutaneous delivery of liquid medications and vaccines with injector, nozzle, nozzle cap and adaptor

This certificate is valid from 18 June 2018 until 18 June 2021
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 20 April 2021
Issue 7. Certified since 29 April 2011

Authorised by

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS 13485 2016 0118

EC Certificate Full Quality Assurance System: Certificate KR18/81825992

The management system of

MIKA MEDICAL CO.

93, Noksansaneopjung-ro, Gangseo-gu, Busan, Republic of Korea

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

Needle free injection system for the subcutaneous delivery of liquid medications and vaccines with injector, nozzle, nozzle cap and adaptor (Model: Comfort-in)

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 18 June 2018 until 18 June 2023
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 20 April 2021
Issue 1. Certified since 18 June 2018

Certification is based on reports numbered KR/SEL Y-PC/11252

Authorised by

SGS United Kingdom Ltd, Notified Body 0120
202B Worle Parkway, Weston-super-Mare, BS22 6WA UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS CE 02 0215