Declaration of Conformity

Manufacturer:
Name: SHANGHAI APOLO MEDICAL TECHNOLOGY Co.,Ltd.
Add: Building 11, Lane 1566, Nanle Road, Songjiang District 201613 Shanghai, P. R. China
Tel: 0086-21-34622842 Fax: 0086-21-34622840

European Representative:
Name: Lotus NL B.V.
Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.
Tel: 0031-645171879

Product Name: Intense Pulsed Light Skin Surface Treatment System (IPL Treatment System)
Classification and relevant Rule of MDD: Ⅱb MDD 93/42/EEC Annex IX, Rule 9
Models: HS-650, HS-660, HS-620, HS-300, HS-310,HS-315
The GMDN code: P 58935
Product Certification Conformity Assessment Route: Annex Ⅱ.3 of MDD 93/42/EEC

We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All technical documentations are retained under the premises of the manufacturer.

DIRECTIVES

General applicable directives:
Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES (MDD 93/42/EEC)

Standard:

EN60601-1: 2006+ A1:2013
EN 60601-2-57-2011
EN ISO 14971:2012
EN 62366-1:2015
ENISO10993-5:2009
EN60601-1-2:2015
EN ISO 13485:2016
EN62304：2006+A1:2015
EN1041：2008+A1:2013
ENISO10993-10:2010

Notified Body： TÜV Rheinland LGA Products GmbH Tillystrasse 2,D-90431 Nurnberg
Identification Number：0197

Registration No.: HD 60145599 0001
Validity of certificate: Mar 31st, 2020
Date CE certificate is expired: May 26th, 2024

Shanghai Apolo Medical Technology Co.,Ltd.