

DECLARATION OF CONFORMITY



We, the manufacturer:

Nanjing Redsun Optical Co.,Ltd.
NO.18 South of Xishangqiao Road of Nanjing,China.
Tel: 0086-25-58575880

EU Representative: LUXUS LEBENSWELT GMB

Address: KOchstr.1, 47877, Willich, Germany

Declare under our sole responsibility that:

Product:Auto refractometer
Model Name: FR8900, AR-7610

Product Group: Ophthalmic Equipment
Classification: Class I (in compliance with Annex I&VII, Medical Device Directive)

Are in conformity with:

Essential Requirements of European Directive(s):
93/42/EEC Medical Device Directive (including 2007/47/EC)

Standard(s):EN60601-1:2006+A1:2013
ISO9001:2008

Test report(s):TRS15060065
ISO13485:2003

The compliance with the European Directive (93/42/EEC) is under the monitoring of the Notified Body:

For and behalf of
NANJING REDSUN OPTICAL CO., LTD.

Signature:Helen He

Export Sale
Manager 2020-10-16

Authorized Signature