



Declaration of Conformity

Manufacturer:	Shanghai Chang'E Optical Equipment&Instrument Technology Co.,Ltd. 1,3/4 Floor #2 Building, No.1515 North Huifeng Road, Fengxian District, Shanghai, China
SRN:	CN-MF-000035114
Authorized EU-Representative:	Riomavix S.L. Calle de Almansa 55, 1D, Madrid 28039 Spain
Basic UDI:	AR7600 697519870AR7600JU ARK7600 697519870ARK7600TW AR7610 697519870AR7610JX ARK7610 697519870ARK7610TZ AR7680 697519870AR7680KL ARK7680 697519870ARK7680UN AR7800L 697519870AR7800LNC ARK7800M 697519870ARK7800M5V AR8100 697519870AR8100JA ARK8100 697519870ARK8100TC AR8600 697519870AR8600K3 ARK8600 697519870ARK8600U5



Product name:	Refracto-Keratometers
Model:	ARK7800L、ARK7800M、AR7600、ARK7600、AR7610、 ARK7610、AR7680、ARK7680、AR8100、ARK8100、 AR8600、ARK8600
EMDN code:	Z129013
Product photograph:	
Basic UDI-DI:	NA
Classification and relevant Rule:	Rule 13, Class 1 according to, Chapter III, Annex VIII classification rules, 2017/745 MDR. Evidence: All other active devices are classified as class I.
Conformity Assessment Route:	MDR 2017/745 Annex XI Part A
Test Standards:	NA IEC60601-1, IEC60601-1-2

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We herewith declare that the above mentioned products meet the provisions of the following EC Council Regulations and Standards. All technical documentations are retained under the premises of the manufacturer. We are exclusively responsible for the declaration of conformity

REGULATIONS

Regulation (EU) 2017/745 of the European Parliament and of the Council.

Name:

陈年

Position:

General
Manager

Date:

2023.5.5

Place:

Shang.China



有限公司