

Official Declaration

Manufacturer: **ZHEJIANG RENON MEDICAL INSTRUMENT CO., LTD**

ADDRESS: **NO.777 EAST HUANZHAN ROAD, HANGZHOU CITY, ZHEJIANG PROVINCE, CHINA**
TEL:**13588016381**

Date: 04/08/2024

To Whom It May Concern,

We, **ZHEJIANG RENON MEDICAL INSTRUMENT CO., LTD**, hereby declare that the laboratory products listed in the attached **Annex A** are intended solely for **general laboratory use**. These products are **not classified as medical devices** or in vitro diagnostic devices (IVD) as defined under **Regulation (EU) 2017/745 (MDR)** and **Regulation (EU) 2017/746 (IVDR)**.

According to **Regulation (EU) 2017/745 (MDR)**, medical devices are defined as "any instrument, apparatus, appliance, software, implant, or similar product intended by the manufacturer for specific medical purposes." None of the products listed in **Annex A** are designed or intended for use in direct human medical treatments or procedures.

As per **Regulation (EU) 2017/746 (IVDR)**, in vitro diagnostic (IVD) devices are defined as "devices intended for the examination of specimens derived from the human body for medical purposes." The products in **Annex A** are not intended to be used in the diagnosis, monitoring, or prevention of medical conditions and are strictly intended for general laboratory applications.

Since these products **do not meet the criteria** for medical devices or IVDs, they are not subject to the **CE marking requirements** under Directives **93/42/EEC** and **98/79/EC**, or under **Regulations (EU) 2017/745** and **2017/746**. Therefore, a **CE Declaration of Conformity** is not required for the products listed in **Annex A**.

Despite not being classified as medical devices, all products are manufactured in accordance with our **ISO 13485:2016-certified Quality Management System**, ensuring strict quality control.

Hence, **registration of these products as medical devices is unnecessary** as they do not fall under the scope of the relevant European medical or IVD regulations.

Sincerely,
ZHEJIANG RENON MEDICAL INSTRUMENT CO., LTD

浙江理能医疗器械有限公司
ZHEJIANG RENON MEDICAL INSTRUMENT CO.,LTD



Annex A - List of Laboratory Products

Glass Beaker Boro 3.3, Glass Flask Boro 3.3, Erlenmeyer Flask, Glass Measuring Cylinder, Boro 3.3, Glass Measuring Cup Boro 3.3, Glass Volumetric Flask Boro 3.3, Reagent Bottle, Glass Funnel, Desiccator, Mortar, Alcohol Lamp, Evaporating Dish, Crystallizing Dish, Watch Glass, Weighing Bottle, Water Tub, Jars Storage for Incubator Use, Culture Flask, Bell Jar, Bell Jar with Stopper, Drying Tower, Gas Generator, Suction Bottle, Suction Bottle, Porcelain Crucible, Porcelain Basins, Porcelain Combustion Boats, Porcelain Funnel with Perforated Filter, Water Tub, Porcelain spotting plates, Plastic Beaker, Plastic Measuring Cylinder, Plastic Measuring Cup, Plastic Volumetric Flask, Wash Bottle

This declaration covers all the products listed in **Annex A**. Each item is specifically intended for laboratory use only and is not subject to registration as a medical or IVD device.

HAIMEN, 2024.08.14

Place, date

General Manager

Function and signature

浙江理能医疗器械有限公司
ZHEJIANG RENON MEDICAL INSTRUMENT CO.,LTD

