

# EC Declaration of Conformity



*Manufacturer:*

**Ningbo Jiangbei Woson Medical Instrument Co., Ltd.**

No.25, Lane 300, Jinshan Road, Jiangbei District,  
Ningbo 315032, China  
Tel: 0086 574 83022668  
Fax: 0086 574 87637357

*whose single Authorized Representative:*

**DTF TECHNOLOGY srl**

via Gressoney 9, 20137 Milano, Italy  
tel: +39.02.84893641  
fax: +39.02.84718594

We, the manufacturer, herewith declare that the products

## **Intraoral Scanner-IONA VISTA**

meet the relevant provisions and requirements of Regulation(EU)2017/745.

The medical device has been assigned to class I according to annex VIII of regulation(EU)2017/745,rule 5 and rule 13 .

Applied harmonised standards, national standards or other normative documents EN 60601-1:2006+A1:2013,EN 60601-1-2:2015,EN 62304:2006+A1:2025.

Compliance of the designated product with the Directive(EU)2017/745 has been assessed and certified by the Notified Body

### **NOT applicable**

following the procedure relating to Module A (EC Declaration of Conformity (Annex IV) +Technical Files).

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above mentioned declaration of conformity is exclusively under the responsibility of

**Ningbo Jiangbei Woson Medical Instrument Co., Ltd.**

2022/08/15 – Ningbo, China  
*Place, date*



Name: Xie Diyan

Position: Vice General Manager

Signature:

*Legally binding signature, Function*