

## EC Declaration of Conformity

*Manufacturer:*

*Authorized Representative:*

**Name:** IntoCare Medical Technology (Suzhou) Co., Ltd.

**Name:** Prolinx GmbH

**Address:** Unit 102/202/301/302/402, East Building 6,  
No.9 West Suhong Road, Suzhou Industrial Park,  
China (Jiangsu) Pilot Free Trade Zone Suzhou Area,  
215000 Jiangsu, P.R. China  
**SRN:** CN-MF-000017686

**Address:** Brehmstr.56, 40239, Duesseldorf Germany  
**SRN:** DE-AR-000005129

We, the manufacturer, herewith declare that the products

### **Reusable Powered Handle**

*GMDN-Code:* **62383**

meets the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class IIa according to Annex IX of the Directive 93/42/EEC.

The product concerned has been manufactured under a quality management system according to Annex II excluding Section 4 of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assured via assessment of the quality management system by the Notified Body

**NOTICE Belgelendirme Muayene ve Denetim Hizmetleri A.Ş**  
**Esentepe Mah. Milangaz Cad, No 75, D91-92-93**  
**Kartal İstanbul, Türkiye**

Registration No.: CE-MDD-0086/03/2020/01

Issue date: 2020.03.25

Expiry date: 2024.05.26

following the procedure relating to the EC Declaration of Conformity set out in Annex II excluding Section 4 of Directive 93/42/EEC.

This Declaration of Conformity covers the medical device as specified in the product list belonging to this declaration and is only valid in connection with a batch specific Certificate of Compliance for all products concerned bearing the CE mark.

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



IntoCare Medical Technology (Suzhou) Co., LTD

Company: IntoCare Medical Technology (Suzhou) Co., Ltd.

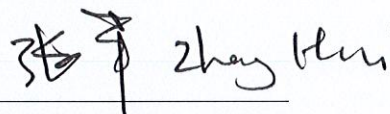
Address: Unit 102/202/301/302/402, East Building 6, No.9 West Suhong Road  
Suzhou Industrial Park, China (Jiangsu) Pilot Free Trade Zone Suzhou Area  
215000 Jiangsu, P.R. China

**Product list:**

Name of the product	Product code and description
Reusable Powered Handle	<ul style="list-style-type: none"><li>- Reusable Powered Handle, Universal (PHD01A) : PHD01, Reusable Powered Handle PHDB01, Rechargeable Li-ion Battery (Accessory) IBA01, Reusable Battery Guide (Accessory) IMT01, Manual Tool (Accessory)</li><li>- PHDA01, Instrument Case (Accessory)</li><li>- PHDC02, Battery Charger (Accessory)</li></ul>

Suzhou, 2022.12.7

Place, date



Legally binding signature, Function

Name: Zhang hui

Position: General Manager