

## EC CERTIFICATE

Annex II excluding section 4 of the Directive 93/42/EEC on Medical Devices

Full Quality Assurance System

Certificate Number

CE-MDD-0086/03/2020/01

Manufacturer : IntoCare Medical Technology (SuZhou) Co., Ltd.

Headquarters : 501#, Building NW-02, Nanopolis Suzhou, No.99 Jinji Lake Avenue, Suzhou Industrial Park, Jiangsu China

Address

Factory : 203#, Building NW-12, Nanopolis Suzhou, No. 99 Jinji Lake Avenue, Suzhou Industrial Park, Jiangsu, China

Product(s) : Reusable Powered Handle

Dimension of reusable powered handle (Unit: mm)

Model(s)

Type	Product Description	Size
PHD01	Reusable Powered Handle	160*91*38

Report Number : CE-MED-0086

First Issue Date and Place : 2020.03.25 &amp; Istanbul

Revision Number and Date : 00 / --

Validity Date : 2024.05.26

NOTICE, Notified Body 2764, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex II (excluding section 4), Section 3 of the directive 93/42/EEC on medical devices. This quality assurance system covers those aspects of manufacturing concerned with securing and maintaining safe conditions of the respective product(s) and conforms to the provisions of this Directive. The approved quality system is subject to surveillance pursuant to Annex II, Section 5 of Directive 93/42/EEC and unannounced audits. NOTICE must be informed of any significant changes in the design and/or construction of the product(s).

Özlem Vıcdan Akdağ  
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