PHCbi

PHC Corporation
1-1-1 Sakada, Oizumi-machi, Ora-gun
Gunma 370-0596, Japan

EC Declaration of Conformity

Document No. PHBM-MR0003-DOC-01

Issuer's / Manufacturer's name, address and SRN

PHC Corporation / 1-1-1 Sakada, Oizumi-machi, Ora-gun, Gunma 370-0596, Japan
SRN: JP-MF-000009698

Objects of the declaration

Product name:	Ultra-Low Temperature Freezer MDF-DU503VXH
Brand / Trade name:	PHCbi
Model No:	MDF-DU503VXH-PE
Applicable serial number:	25070001 and subsequent number
Basic UDI-DI:	4987905FREEZEREY

This Declaration of Conformity is issued under the sole responsibility of the manufacturer.

EU legislation

Regulation:	Regulation (EU) 2017/745 2011/65/EU
Classification:	Class IIa (Rule 2 of Annex VIII, MDR)
Common Specification:	Not applicable

Intended purpose

This equipment is designed for storage of blood and blood products.

Notified Body

TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 München, Germany

Identification Number: CE 0123

EC certificate

Certificate No.:	G20 003951 0005 Rev. 01
Conformity assessment procedure:	MDR Annex XI

The last two digit of the year in which the CE marking was firstly affixed: 25
Additional Information:

We hereby declare that under our sole responsibility aforementioned objects comply with the provisions of the national law transposing aforementioned EU legislations.
All supporting documentation is retained under the premises of the manufacturer.

Signed for and on behalf of:

C. Takauo

(Printed Name) Chikara Takauo
(Title) Director of Biomedical Division
Place and date of issue: 31 July, 2025, Gunma

Authorised Representative in EU

(Date) 08/08/2025
(Signature)
(Printed Name) Martin van Gelderen
(Company Name) PHC Europe B.V.
(Address) Eikdonk 1, 4825 AZ, Breda, The Netherlands