Plan1Health
A Poly Medicure Group company

Regulation (EU) 2023/607 amending Regulation (EU) 2017/745
Transitional provisions

To whom it may concern

Plan 1 Health S.r.l., located in Via Fratelli Solari 5, 33020 Amaro (UD) - Italy, manufacturer of medical devices covered by the certificates listed in below table, issued under the Medical Device Directive 93/42/EEC on 15 January 2018, by Dekra Certification BV and expired on the 1st of December 2022:

Certificate n.	Certificate Type	Product categories
2126204CE01	Full Quality Assurance System Directive 93/42/EEC on Medical devices, Annex II excluding (4)	Implantable Access System and associated Introducer Sets, invasive Drug Delivery Devices for Administration of Pain Medication
2126204DE01	EC Design-Examination Directive 93/42/EEC on Medical devices, Annex II (4) (Device in Class III)	HealthPort Implantable Access Port System (Venous and Spinal) Including Sets
2126204DE03	EC Design-Examination Directive 93/42/EEC on Medical devices, Annex II (4) (Device in Class III)	SecurePort Implantable Access Port System (Venous and Spinal) Including Sets
2126204DE04	EC Design-Examination Directive 93/42/EEC on Medical devices, Annex II (4) (Device in Class III)	HealthPICC: Implantable Central venous Catheter System, peripherally inserted

By applying the provisions of article 1 of **Regulation (EU) 2023/607** which amends Regulation (EU) 2017/745 as regards the transitional provisions for certain medical devices,

DECLARES that

the certificates mentioned above are considered valid until 31 December 2027 or, until the date of issue of the new certificates in accordance with Regulation (EU) 2017/745, considering that the following condition is satisfied:

a) before the expiry date of the certificate, Plan 1 Health and the notified body signed a written agreement in accordance with Annex VII, point 4.3, second paragraph, of Regulation (EU) 2017/745, for the conformity assessment of the device covered by the expired certificate or a device intended to replace such a device;

Digitally signed by Șarco Alexandru
Date: 2023.10.11 17:41:48 EEST
Reason: MoldSign Signature
Location: Moldova

PLAN 1 HEALTH S.r.l.
(sottoposta al controllo unico di Poly Medicure BV-*under the sole control of Poly Medicure BV*)
Sede Legale- *Legal Site*: Via Fratelli Solari 5 - 33020 Amaro (UD) – Italia
Tel. +39 0433 468376 – Fax: +39 0433 468383
info@p1h.it – web: www.p1h.it – codice SDI A4707H7
CF e P. IVA- *Tax Code and VAT*: IT 01677460303
CCIAA – *Company Registry* Udine n. 187930
Capitale Sociale – *Social Capital* –Euro 1.755.000,00 i.v. *(f.p).*

Plan 1 Health also confirms that the following conditions set out in Article 1, paragraph 3 quater of Regulation (EU) 2023/607 are fully satisfied:

a) such devices continue to comply with Directive 90/385/EEC or Directive 93/42/EEC, as the case may be;
b) there are no significant changes in the design and intended use;
c) the devices do not present an unacceptable risk to the health or safety of patients, users or other persons or to other aspects of public health protection;
d) the manufacturer has set up a quality management system in accordance with article 10, paragraph 9 of Regulation 2017/745;
e) the manufacturer has already lodged a formal application with a notified body in accordance with the first paragraph of point 4.3 of Annex VII for conformity assessment of devices covered by the above certificates and, the notified body and the manufacturer have already signed a written agreement in accordance with Annex VII, point 4.3, second paragraph of Regulation 2017/745.

The Quality Management System certificate according EN ISO 13485 is still in focre with certificate n. 2182609 and remain valid till 30 June 2024.

Date: 22 March 2023

Place: Amaro (UD) Italy

Signature:

Name: Luca Giorgini

Position: Managing director and Company Representative

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