

Declaration for Use of the Extended Transitional Period
Article 120 - Regulation (EU) 2017/745

Article 120 in Regulation (EU) 2017/745 has been amended by Regulation (EU) 2023/607 to extend the transitional period for legacy devices beyond 26 May 2024, providing certain conditions are fulfilled.

This letter confirms that the products listed in Appendix 1 were covered by a valid certificate issued by a Notified Body (BSI The Netherlands; 2797) in accordance with Directive 93/42/EEC after 20 March 2023. The listed products are therefore eligible to avail of the extended transitional periods as per Article 120(3a) in Regulation (EU) 2017/745, as amended.

For the extended transitional period to apply, the following conditions stated in Article 120(3c) shall be met:

- (a) those devices continue to comply with Directive 90/385/EEC or Directive 93/42/EEC, as applicable;
- (b) there are no significant changes in the design and intended purpose;
- (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 the protection of public health;
- (d) no later than 26 May 2024, the manufacturer has put in place a quality management system in accordance with Article 10(9);
- (e) no later than 26 May 2024, the manufacturer or the authorised representative has lodged a formal application with a notified body in accordance with Section 4.3, first subparagraph, of Annex VII for conformity assessment in respect of a device referred to in paragraph 3a or 3b of this Article or in respect of a device intended to substitute that device, and, no later than 26 September 2024, the notified body and the manufacturer have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII.

As Legal Manufacturer, we - Convatec Limited, First Avenue, Deeside Industrial Park, Deeside, Flintshire, CH5 2NU, United Kingdom (SRN: GB-MF-000001770), - hereby declare, under our sole responsibility, that the conditions for the extension of the transitional period as stated in Article 120(3c) in Regulation (EU) 2017/745, as amended by Regulation (EU) 2023/607, are fulfilled. The products listed in Appendix 1 can thereby be placed on the market or put into service until the following dates:

Class III and class IIb implantable devices:	31 December 2027.
Class IIb (non-implantable), class IIa and class I (sterile/measuring) devices:	31 December 2028.

DocuSigned by:

Signer Name: Steeve Lamvohee
Signing Reason: I approve this document
Signing Time: Jun 30, 2023 | 8:07:32 PM BST
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Jun 30, 2023

Steeve Lamvohee

Issue Date

Head of IC/AWC Regulatory Affairs

Appendix 1: Product List

Device Name	Basic UDI	MDR Device Classification	Transitional Period End Date	MDD Certificate Reference	MDD Certificate Expiry Date	Notified Body #
Aquacel Surgical Cover Dressing	768455AWC00203C	Class III	31/12/2027	CE 00364 CE 00380	20/10/2023 26/05/2024	2797 2797
Duoderm Extra Thin	768455AWC00303F	Class III	31/12/2027	CE 00364 CE 00380	20/10/2023 26/05/2024	2797 2797
Duoderm Signal	768455AWC00313H	Class III	31/12/2027	CE 00364 CE 00380	20/10/2023 26/05/2024	2797 2797
Duoderm CGF	768455AWC00323K	Class III	31/12/2027	CE 00364 CE 00380	20/10/2023 26/05/2024	2797 2797
Duoderm CGF Border	768455AWC00293W	Class III	31/12/2027	CE 00364 CE 00380	20/10/2023 26/05/2024	2797 2797
Aquacel Foam	768455AWC00063J	Class IIb (non-implantable)	31/12/2028	CE 00364	20/10/2023	2797
Aquacel Foam Pro	768455AWC00073L	Class IIb (non-implantable)	31/12/2028	CE 00364	20/10/2023	2797
Aquacel Extra & WSF	768455AWC00213E	Class IIb (non-implantable)	31/12/2028	CE 00364	20/10/2023	2797
Carboflex	768455AWC00083N	Class IIb (non-implantable)	31/12/2028	CE 00364	20/10/2023	2797
Duoderm Gel	768455AWC00093Q	Class IIb (non-implantable)	31/12/2028	CE 00364	20/10/2023	2797
Convatec Foam Lite	768455AWC00193T	Class IIb (non-implantable)	31/12/2028	CE 00364	20/10/2023	2797
Kaltostat	768455AWC00053G	Class IIb (non-implantable)	31/12/2028	CE 00364	20/10/2023	2797
Avelle NPWT Dressing	768455AWC00033C	Class IIb (non-implantable)	31/12/2028	CE 00364	20/10/2023	2797
Avelle NPWT Pump	768455AWC00023A	Class IIa	31/12/2028	CE 00364	20/10/2023	2797
Hydrocolloid Sealing Strips	768455AWC00163M	Class Is	31/12/2028	CE 56172	20/10/2023	2797
Loop Ostomy Rod	768455OST0005F5	Class IIa	31/12/2028	CE 00364	20/10/2023	2797