



Manufacturer's Declaration of Conformity

Declaration Identity: Dirinco BV - DoC Citra-Lock Vials – 02-12-2020

Dirinco BV, located at Ketelmeer 1, 5347 JX Oss, The Netherlands, declares on its own and exclusive responsibility that the Citra-Lock™ solutions identified in Table 1 below,

- Have been classified according to the classification rules of Annex IX of the Directive 93/42/EEC as amended by Directive 2007/47/EC;
- Comply with the applicable Essential Principles for Safety and Performance in Annex I of Directive 93/42/EEC as amended by Directive 2007/47/EC, as demonstrated by the technical documentation ('CE Master File');
- Have met the applicable requirements of the conformity assessment procedure referred to in Annex II, excluding section 4 of the Directive 93/42/EEC as amended by Directive 2007/47/EC.

Dirinco BV also undertakes to maintain the Quality Management System already implemented, in compliance with the current EN ISO 13485 requirements as verified by the Notified Body 0197, TÜV Rheinland LGA Products GmbH; Nürnberg, Germany (audit reports on file). Dirinco BV confirms that no other application has been lodged with another Notified Body for the same products and product-related Quality Management System.

Table 1: Device information

Legal Manufacturer	Dirinco BV, Oss The Netherlands. Dirinco BV Ketelmeer 1 5347 JX Oss T +31 (0)73 521 8880 F +31 (0)412 633 554 E info@dirinco.com BTW nr NL 0069.48.571 B01 KvK nr 16050841 www.dirinco.com IBAN NL04 INGB 0674 3912 84 BIC (SWIFT) INGBNL2A
Name of the Device Family	Citra-Lock™
Products Included	<ul style="list-style-type: none"> • Citra-Lock™ 4%, 5mL PE vials • Citra-Lock™ 30%, 5mL PE vials • Citra-Lock™ 46.7%, 5mL PE vials
Devices in their primary packaging	
Intended Purpose	<ul style="list-style-type: none"> • Citra-Lock™ 4% Anticoagulant for use as catheter lock. • Citra-Lock™ 30% Anticoagulant, antimicrobial, and reducing biofilm formation, used as a catheter lock. • Citra-Lock™ 46.7%



	Anticoagulant, antimicrobial, and reducing biofilm formation, used as a catheter lock.
Mode of Contact	The solutions are not intended to be in contact with the patients. <u>They are used as catheter lock.</u>
Shelf-Life	3 years
Device Class and Classification Rules	All solutions are class IIb medical devices, as per Rule 3.
CE Certificate Number (current)	HD 60148183 0001 Effective Date: 2020-03-26 Expiry Date: 2024-05-26 Issued by Notified Body 0197: TÜV Rheinland LGA Products GmbH, Nürnberg Germany.

Declaration authorized by:

Oss, NL

2 December 2020

Maha Haimour, Director, place of signature and date of signature

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