

Declaration of Conformity

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

MANUFACTURER		
Name of Company	Address	SRN
Terragene S.A.	Ruta Nacional Nº 9, km 280, Parque Industrial Micropi, CP 2130, Alvear, Santa Fe, Argentina	N/A

AUTHORIZED REPRESENTATIVE			
Name of Company	Address	SRN	Phone/email
Emergo Europe	Westervoortsedijk 60 6827 AT Arnhem The Netherlands	NL-AR-000000116	+31.70.345.8570 EmergoEurope@ul.com

PRODUCT IDENTIFICATION	
Device Family Name	Device Trade Name
Terragene® Cleaning, disinfection and sterilization indicators.	Terragene Chemdye Terragene Cintape Terragene Integron Terragene Chemink Terragene Bionova
Intended Purpose	Basic UDI-DI
For monitoring sterilization, cleaning and disinfection processes of medical devices.	779816467CI5L

RISK CLASS FOR DEVICES		
Device Classification		Common Specifications / Standards
Class:	I	
Rule:	1	

Terragene S.A. declares that the above-mentioned products meet the provision of the following EU legislation:

- Medical Devices Regulation (EU) 2017/745

COMPANY REPRESENTATIVE: Adrián Jesús Rovetto

TITLE: Technical Director

SIGNATURE:



TERRAGENE S.A.
Lic. Adrián Rovetto
DIRECTOR TÉCNICO

PLACE: Alvear, Santa Fe, Argentina

DATE: 03/02/2023