

## **EC-Declaration of Conformity for Medical Devices**

(in accordance with annex VII of the Council Directive for Medical Devices 93/42/EEC)

**Name of manufacturer:** VOCO GmbH

**Address:** Anton-Flettner-Straße 1 - 3  
27472 Cuxhaven  
Germany

We declare that the product

**Article:** Registrado X-tra

**Type:** Addition-curing silicone for bite registration, extra hard, fast setting

**Item Number:** see annex

**Class:** I

**Rule:** 5

corresponds to the regulations of the following Council Directive :

**93/42/EEC for Medical Devices**

and that we take full responsibility for issuing this declaration.

**Name and address of notified body**

**MedCert GmbH**  
**Pilatuspool 2**  
**20355 Hamburg**  
**Germany**  
**Identification number : 0482**

**Valid up to 5 years after issue or revision of the technical documentation**

City: Cuxhaven

Date: February 15, 2021

*Dr. A. Leitz*

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Regulatory Affairs

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(in accordance with annex VII of the Council Directive for Medical Devices 93/42/EEC)

**Name of manufacturer:** VOCO GmbH

### ANNEX

**Article:** Registrado X-tra

REF #	Description
2035	Cartridge 2 × 50 ml
2036	Cartridge 8 × 50 ml

City: Cuxhaven

Date: February 15, 2021

*Dr. A. Lenz*

Regulatory Affairs