

## DECLARATION OF CONFORMITY CE

**Declaration of conformity of the family of Medical Device “UCS® DEBRIDEMENT”  
manufactured by WELCARE Industries SpA with registered office in via San Giovanni sul  
Muro, 18 – 20121 Milano-Italy**

CODE	DESCRIPTION
95150	UCS® DEBRIDEMENT 20X20cm, Sterile -Dispenser with 30 pouches
95150F	UCS® DEBRIDEMENT 20X20cm, Sterile -Dispenser with 10 pouches
95160	UCSol™ DEBRIDEMENT, Sterile-Dispenser with 12 bottles, 150 ml each
95160F	UCSol™ DEBRIDEMENT, Sterile- Bottle150 ml
95170	UCSol™ DEBRIDEMENT, Sterile-Dispenser with 12 bottles, 500 ml each
95180	UCGel™ DEBRIDEMENT, Sterile, 20 airless bottles, 15 ml each
95181	UCGel™ DEBRIDEMENT, Sterile, 5 airless bottles, 50 ml each

*states that the above medical devices are certified in accordance with the provisions of Annex II of Directive 93/42 EEC (as amended and supplemented by Directive 2007/47 EC transposed by Legislative Decree 37/2010) and Article 120 of EU Regulation 745/2017, as amended by EU Regulation 607/2023 regarding transitional provisions.*

Therefore, Welcare Industries SpA states that:

- The Medical Device obey to the essential requirements of Annex I of the Directive 93/42/EEC;
- The Medical Device is certified according to Annex II of the Directive 93/42/EEC;
- The Medical Device is classified in Class IIb in according to the rule n°4<sup>1</sup>, Annex IX of The Directive 93/42/EEC;
- The Medical Device is not measuring device;
- The Medical Device is not used for clinical evaluations;
- The Medical Device is sterile;
- The Medical Device is manufactured in accordance with the certified Quality System;
- The product documentation is available at Welcare Industries SpA and will be properly stored for five years since the latest date of market introduction;
- The Medical Device is marked CE<sub>0373</sub>.

Milano, 30.01.2025

WELCARE INDUSTRIES SpA

CEO

Fulvia Lazzarotto

<sup>1</sup>All non-invasive devices which come into contact with injured skin:

- are in Class IIb if they are intended to be used principally with wounds which have breached the dermis and can only heal by secondary intent.

