WELCARE
PROTECTING PEOPLE, CARING FOR NATURE

DECLARATION ABOUT MEDICAL DEVICE "UCS® DEBRIDEMENT "

manufactured by WELCARE Industries SpA with registered office in via San Giovanni sul Muro, 18 – 20121 Milano-Italy

CODE	DESCRIPTION
95150G	UCS® DEBRIDEMENT 13X10cm, Sterile -Dispenser with 30 pouches

States that the Medical Devices follows the essential requirements of the directive 93/42/EEC in force in Italy with Decree n°46, February 24th 1997 as amended and supplemented by Directive 2007/47EEC implemented by Decree n.37/2010.

Therefore, Welcare Industries SpA states that:

- the above Medical Device is 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;
- The Medical Device is classified in Class IIb in according to the rule n°41, 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 CE0373.

Milano, 16.05.2025

WELCARE INDUSTRIES SpA

CEO

Fulvia Lazzarotto

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