


## CERTIFICATE OF CONFORMITY

### MDD 93/42/EEC

<b>MANUFACTURER:</b>	CF Pharma Ireland Ltd.
<b>ADDRESS</b>	Unit 73B, Hebron Industrial Estate, Kilkenny, Ireland. Tel: ++353 51 439010
<b>SRN No.</b>	SRN number is IE-MF-00004595
<b>CUSTOMER:</b>	W.Soehngen GmbH, Platter Str.84, Taunusstein, Germany
<b>PRODUCTS:</b>	Medical Device Wound Irrigation Solution Preserved With Hypochlorous Acid - AluDerm 60ml Hydrogel
<b>BATCH NUMBER/EXPIRY:</b>	C1557A, 2027-03 - Quantity 3,000 units
<b>CLASSIFICATION:</b>	Class IIa Medical Device, Rule 4
<b>DECLARATION:</b>	<p>We herewith declare that the above-mentioned products meet the provisions of:</p> <ul style="list-style-type: none"> <li>Compliance to essential requirements of the Directive 93/42/EEC and subsequent amendments.</li> <li>Classification Rule: Evaluation of the conformity (Annex V) of the Directive 93/42/EEC</li> </ul> <p>The Medical Device is manufactured according to Technical File CFTF009 Rev 18 and meets the provision of that document. All supporting documentation is retained under the premises of CF Pharma.</p>
<b>STANDARDS APPLIED:</b>	Certificate Number 576DM05, Quality Management System in Compliance with standard UNI CEI EN ISO 13485-2021(ISO 13485-2016).
<b>NOTIFIED BODY:</b>	ITALCERT Srl, Viale Sarca, 336, IT 20126 Milano, Italy
<b>EC CERTIFICATE(S):</b>	Certificate NO. 494-00-00-DM in compliance with Annex V of the directive 93/42/EEC. Number 0426.
<b>SIGNATURE:</b>	<div style="display: flex; justify-content: space-between; align-items: center;"> <div style="text-align: center;">               Clare Hughes, MPSI BSC Pharma              CEO CF Pharma Ireland Ltd.           </div> <div style="text-align: right;">             Date: <u>5-3-2025</u> </div> </div>