


CERTIFICATE OF CONFORMITY

MDD 93/42/EEC

MANUFACTURER:	CF Pharma Ireland Ltd.
ADDRESS	Unit 73B, Hebron Industrial Estate, Kilkenny, Ireland. Tel: ++353 51 439010
SRN No.	SRN number is IE-MF-00004595
CUSTOMER:	W.Soehngen GmbH, Platter Str.84, Taunusstein, Germany
PRODUCTS:	Medical Device Wound Irrigation Solution Preserved With Hypochlorous Acid - AluDerm 60ml Hydrogel
BATCH NUMBER/EXPIRY:	C1558A, 2027-03 - Quantity 2,007 units
CLASSIFICATION:	Class IIa Medical Device, Rule 4
DECLARATION:	<p>We herewith declare that the above-mentioned products meet the provisions of:</p> <ul style="list-style-type: none"> Compliance to essential requirements of the Directive 93/42/EEC and subsequent amendments. Classification Rule: Evaluation of the conformity (Annex V) of the Directive 93/42/EEC <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>
STANDARDS APPLIED:	Certificate Number 576DM05, Quality Management System in Compliance with standard UNI CEI EN ISO 13485-2021(ISO 13485-2016).
NOTIFIED BODY:	ITALCERT Srl, Viale Sarca, 336, IT 20126 Milano, Italy
EC CERTIFICATE(S):	Certificate NO. 494-00-00-DM in compliance with Annex V of the directive 93/42/EEC. Number 0426.
SIGNATURE:	<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>