


Document name Declaration of Conformity	Version 02	Document number 1.2	
Issued by Tilda Kallur/ QA	Date 2024-10-03	Intended audience All	
Approved by Tilda Kallur/ QA	Datum 2025-02-19	Valid from 2025-02-19	

## EG-FÖRSÄKRAN ON ÖVERENSSTÄMMELSE / EC DECLARATION OF CONFORMITY

Dokumentnummer / Document No.:	Declaration of Conformity 1.2
Tillverkare / Manufacturer:	Sacci AB
Adress / Address:	Gamla Tunavägen 8 SE-784 35 Borlänge Sweden
Produkt för deklARATION / Object of declaration:	111521 Infusion Thermo Bag / Infusionsautomaten
Överensstämmer med kraven i följande EU-direktiv / Complies with the requirements of the following EU directives:	Förordning (EU) 2023/988 – Allmän produktsäkerhet (GPSR) / General Product Safety Regulation (GPSR) Direktiv 2011/65/EU – Begränsning av användningen av vissa farliga ämnen i elektrisk och elektronisk utrustning (RoHS), / Restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

## PRODUKTIDENTIFIKATION (ARTIKELNR) / DEVICE IDENTIFICATION (PART NO.):


Produktnamn/ Product Name	Artikelnr/ Part No.	Beskrivning, Version, etc. / Description, Version, etc.
Infusionsautomat / Infusion thermo bag 3 litre	111521	<p>Infusionsautomaten är en isolerad värmeväska med plats upp till tre 1L infusionspåsar som värmer infusionslösningar till kroppstemperatur i ambulansen. Detta främjar administration av kroppstempererade infusionslösningar i ett tidigt skede.</p> <p>The Infusion Thermo bag 3 litre is an insulated thermo bag which can hold up to three pieces of 1 L infusion solution bags that heats infusion solutions to body temperature inside the ambulance. This promotes the administration of infusion solution with body temperature at an early stage.</p>

Vi, Sacci AB, intygar härmed på vårt eget ansvar att angiven produkt, infusionsautomaten, överensstämmer med tillämplig unionslagstiftning och uppfyller de tillämpliga kraven i General Product Safety Regulation (EU 2023/998 GPSR) och Restriction of Hazardous Substances (RoHS 2011/65/EU).

*Ändringar av produkten, som ej godkänts av oss gör denna deklARATION ogiltig.*

We, Sacci AB, hereby declare under our sole responsibility that the product, Infusion Thermo bag, is in conformity with the relevant Union harmonisation legislation and is in conformity with the applicable requirements in General Product Safety Regulation (EU 2023/998 GPSR) and Restriction of Hazardous Substances (RoHS 2011/65/EU).


*Any modification to the device, not authorized by us, will invalidate this declaration.*

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ÖVERENSSTÄMMER MED FÖLJANDE DIREKTIV OCH STANDARDER / COMPLIES WITH THE FOLLOWING DIRECTIVES AND STANDARDS

Harmoniserad standard / Harmonised standard	Beskrivning / Description
EN 60601-1:2014	Electrical Safety Medical devices
EN 55011:2009+A1:2010	Industrial, scientific and medical equipment. Radio-frequency disturbance characteristics. Limits and methods of measurement
IEC 61000-3-2:2014	Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions
61000-3-3:2013	Electromagnetic compatibility (EMC) - Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current $\leq 16$ A per phase and not subject to conditional connection
EN 60601-1-2:2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests
EN 61000-4-2:2009	Electromagnetic compatibility (EMC) - Part 4-2: Testing and measuring techniques - Electrostatic discharge immunity test
EN 61000-4-3:2006	Electromagnetic compatibility (EMC) - Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test
EN 61000-4-8:2010	Electromagnetic compatibility (EMC) - Testing and measurement techniques. Power frequency magnetic field immunity test

UNDERTECKNAD AV / SIGNED BY:

<p>Borlänge 2025-02-19</p> <p>Ort och datum/Place and date</p>
<p></p> <p>Namn/teckning/Signature:</p>
<p>Julia Siklander</p> <p>Namn/förtydligande/Printed name</p>
<p>COO</p> <p>Befattning/Position</p>