Angelini Pharma	Form Quality System

Medical Devices: EU Declaration of Conformity (MDR)

Document Number	Version	Status	Effective Date (*based on server time zone)
FORM-000006705	2.0, CURRENT	Effective	07-Jun-2023

Applicable Sites: Headquarter

Applicable Area: Quality System

Artifact Name: Product Industrialization & Lifecycle

Scope: Angelini Group Companies

DICHIARAZIONE DI CONFORMITA' UE

EU DECLARATION OF CONFORMITY

La presente dichiarazione è valida per tutti i lotti prodotti fino al
This declaration is valid for all batches produced before ***15/06/2024***

FABBRICANTE **MANUFACTURER** nome e indirizzo della sede legale name and the address of their registered place of business	**Angelini Pharma Inc.** 1231 Wyandotte Drive Albany GA 31705 USA
NUMERO DI REGISTRAZIONE UNICO (FABBRICANTE) **SINGLE REGISTRATION NUMBER (MANUFACTURER)**	Requested - not yet available
MANDATARIO **AUTHORISED REPRESENTATIVE** nome e indirizzo della sede legale name and the address of their registered place of business Where applicable	**Angelini Pharma S.p.A.** Viale Amelia 70 00181 Rome Italy
NUMERO DI REGISTRAZIONE UNICO (MANDATARIO) **SINGLE REGISTRATION NUMBER (AUTHORISED REPRESENTATIVE)** Where applicable	IT-AR-000028426
BASIC UDI-DI	08600065397TC3LBH800000WF
NOME DEL PRODOTTO E DENOMINAZIONE COMMERCIALE **E RELATIVA DESTINAZIONE D'USO** **PRODUCT AND TRADE NAME AS WELL AS ITS INTENDED PURPOSE**	**ThermaCare Heatwraps (Lower Back and Hip 8 hours)** THERMACARE LBH 8HR 4CT DE-AT-CH THERMACARE LBH 8HR 4CT FR-BE THERMACARE LBH 8HR 2CT UK - IE THERMACARE LBH 8HR 2CT DE-AT-CH THERMACARE LBH 8HR 2CT IT THERMACARE LBH 8HR 2CT FR-BE THERMACARE LBH 8HR 2CT NL THERMACARE LBH 8HR 4CT IT THERMACARE LBH 8HR 2CT SP-PT

	THERMACARE LBH 8HR 4CT SP-PT THERMACARE LBH 8HR 4CT NL THERMACARE LBH 2CT NO-SE-FI-DK THERMACARE LBH 8HR 6CT DE-AT-CH THERMACARE LBH 8HR 1CT DE-AT-CH THERMACARE LBH 8HR 1CT DE-AT THERMACARE LBH 8HR 2CT PL-RO THERMACARE LBH 8HR 4CT PL I prodotti sono dispositivi medici monouso disponibili sotto forma di fascia termica, destinati a fornire 8 ORE di calore costante per un sollievo efficace, mirato e prolungato di dolori muscolari e/o articolari associati a: sforzi eccessivi, stiramenti e distorsioni, artriti, tensioni muscolari. Indicato per chi soffre di dolori acuti, cronici e occasionali. La fascia per la parte bassa della schiena e dell'anca è fissata alla parte bassa della schiena e/o all'anca con un sistema di fissaggio a cintura elastica. The products are single use medical devices available as a heat wrap, intended to provide 8 HOURS of constant heat for effective, targeted and prolonged relief of muscle and/or joint pains associated with: overexertion, strains and sprains, arthritis, muscle tension. Suitable for those suffering from acute, chronic and occasional pain. The Lower Back and Hip wrap is attached to the lower back and/or hip with an elastic belt fastening system.
CODICE DEL PRODOTTO **PRODUCT CODE**	F00573301009W F00573301015W F00573301020W F00573301023W F00573301024W F00573301025W F00573301026W F00573301028W F00573301033W F00573301034W F00573301053W F00573301062W F00573301064W F00573301080W F00573301093W F00573304001 F00573304002
CLASSE DI RISCHIO CONFORMEMENTE ALLE REGOLE DI CUI ALL'ALLEGATO VIII	**Class IIa** in compliance with Annex IX excluding chapter II, Rule 9 Regulation (EU) 2017/745 (MDR)

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RISK CLASS IN ACCORDANCE WITH THE RULES SET OUT IN ANNEX VIII	
DICHIARAZIONE **DECLARATION**	**SI DICHIARA CHE IL DISPOSITIVO MEDICOV SOPRA MENZIONATO E' CONFORME AL REGOLAMENTO (UE) 2017/745** WE HEREWITH DECLARE THAT THE ABOVE-MENTIONED MEDICAL DEVICE COMPLIES WITH THE REGULATION (EU) 2017/745
NORME STANDARD APPLICATE **APPLIED STANDARDS**	EN ISO 13485:2016; EN ISO 14971:2019; ISO 14155:2020 ISO 15223-1:2021; ISO 20417:2021; ISO 10993-1:2018; ISO 10993-5:2009; ISO 10993-10:2021; ISO 10993-23:2021; ISO 10993-18:2020**;** IEC 62366-1:2015; ASTM D4332-14; ASTM D4169-16; ASTM F1886.
ORGANISMO NOTIFICATO **NOTIFIED BODY** **NUMERO DI IDENTIFICAZIONE** **IDENTIFICATION NUMBER** Where applicable	TÜV SÜD Product Service GmbH - Ridlerstrasse 65 - 80339 Munich – Germany. N. CE 0123
CERTIFICATO CE N° **EC CERTIFICATE N°**	N° G10 112638 0001 Rev.00 **Scadenza**: 2027-08-29 **Expiry date: 2027-08-29** **DESCRIZIONE DELLA PROCEDURA DI VALUTAZIONE DELLA CONFORMITA':** **DESCRIPTION OF THE CONFORMITY ASSESSMENT PROCEDURE** Annex IX, Chapter I & III| IIa, IIb |EU Quality Management System Certificate (MDR) | G10

Questa Dichiarazione di Conformità è rilasciata sotto l'esclusiva responsabilità del Fabbricante
This declaration of conformity is issued under the sole responsibility of the manufacturer

LUOGO E DATA DI RILASCIO:
PLACE AND DATE OF ISSUE: Albany, *15/06/2023*

NOME E FUNZIONE
NAME AND FUNCTION Rebecca Ethridge
Quality Lead/ PRRC
Angelini Pharma Inc.

FIRMA:
SIGNATURE: Rebecca Ethridge

Digitally signed by Rebecca Ethridge
Date: 2023.06.13 10:26:10 -04'00'

(PER CONTO DEL FABBRICANTE SOPRA RIPORTATO)
(ON BEHALF OF THE ABOVE INDICATED LEGAL MANUFACTURER)