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	08600065397TC5NSW800000KU
NOME DEL PRODOTTO E DENOMINAZIONE COMMERCIALE **E RELATIVA DESTINAZIONE D'USO** **PRODUCT AND TRADE NAME AS WELL AS ITS INTENDED PURPOSE**	**ThermaCare Heatwraps (Neck Shoulder and Wrist 8 hours)** THERMACARE NSW 8HR 2CT SP-PT THERMACARE NSW 8HR 6CT FR-BE THERMACARE NSW 8 HR 2CT IT THERMACARE NSW 8HR 2CT FR-BE THERMACARE NSW 8 HR 6CT IT THERMACARE NSW 8 HR 3CT NL THERMACARE NSW 8HR 6CT SP-PT THERMACARE NSW 8 HR 6CT NL THERMACARE NSW 3 CTS NO-SE-FI-DK THERMACARE NSW 8HR 2CT PL-RO

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

	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 collo, spalle e polsi viene applicata direttamente al collo, alla spalla o al polso con linguette autoadesive. 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 Neck Shoulder and Wrist wrap is applied directly to the neck, shoulder or wrist with self-adhesive tabs.
CODICE DEL PRODOTTO **PRODUCT CODE**	F00573301505W F00573301515W F00573301524W F00573301525W F00573301528W F00573301533W F00573301536W F00573301566W F00573301570W F00573304004
CLASSE DI RISCHIO CONFORMEMENTE ALLE REGOLE DI CUI ALL'ALLEGATO VIII **RISK CLASS IN ACCORDANCE WITH THE RULES SET OUT IN ANNEX VIII**	**Class IIa** in compliance with Annex IX excluding chapter II, Rule 9 Regulation (EU) 2017/745 (MDR)
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**

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

	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: Rebecca Ethridge Digitally signed by Rebecca Ethridge Date: 2023.06.13 10:27:17 -04'00'
SIGNATURE: _____

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