



Déclaration de conformité UE - EU Declaration of conformity

Cette déclaration de conformité est établie sous la seule responsabilité du fabricant légal :
This declaration of conformity is issued under the sole responsibility of the legal manufacturer:

Fabricant / Manufacturer	THUASNE
Adresse / Address	120 rue Marius AUFAN, 92300 Levallois-Perret, France
Numéro d'enregistrement unique / Single registration number (SRN)	FR-MF-000001201

Cette déclaration certifie que - *This is to certify that:*

Référence / Reference	Désignation / Description	Basic UDI-DI
720002	Argicalm - Reusable Thermic clay pack - International pack	311179FR0075AFG
720003	Argicalm - Reusable Thermic clay pack - Eastern Europe pack	
720004	Argicalm Hot and cold pack Argicalm Cold mask Argicalm Hot and cold pack for kid - International pack	
720005	Argicalm Hot and cold pack Argicalm Cold mask Argicalm Hot and cold pack for kid - Eastern Europe pack	
720006	Argicalm Hot and cold pack - International pack	





Code article / article code	Variants / Variants	UDI-DI
72000220105699	Reusable Thermic clay pack Size 1- International pack	3111797200065
72000220205699	Reusable Thermic clay pack Size 2- International pack	3111797200072
72000220305699	Reusable Thermic clay pack Size 3- International pack	3111797200089
72000220405699	Reusable Thermic clay pack Size 4- International pack	3111797200096
72000320105699	Reusable Thermic clay pack Size 1- Eastern Europe pack	3111797200133
72000320205699	Reusable Thermic clay pack Size 2- Eastern Europe pack	3111797200140
72000320305699	Reusable Thermic clay pack Size 3- Eastern Europe pack	3111797200157
72000320405699	Reusable Thermic clay pack Size 4- Eastern Europe pack	3111797200164
72000420105699	Argicalm Hot and cold pack Size 1-International pack	3111790055099
72000420205699	Argicalm Hot and cold pack Size 2-International pack	3111790055105
72000420205699	Argicalm Hot and cold pack Size 3-International pack	3111790055112
72000420405699	Argicalm Hot and cold pack Size 4-International pack	3111790055129
72000429905699	Argicalm Cold mask- International pack	3111790055136
72000420005699	Argicalm Hot and cold pack for kids- International pack	3111790055082
72000520105699	Argicalm Hot and cold pack Size 1- Eastern Europe pack	3111790055150
72000520205699	Argicalm Hot and cold pack Size 2- Eastern Europe pack	3111790055167
72000520305699	Argicalm Hot and cold pack Size 3- Eastern Europe pack	3111790055174
72000520405699	Argicalm Hot and cold pack Size 4- Eastern Europe pack	3111790055181





72000529905699	Argicalm Cold mask- Eastern Europe pack	3111790055198
72000520005699	Argicalm Hot and cold pack for kids- Eastern Europe pack	3111790055143
72000620105699	Argicalm Hot and cold pack Taille / Size 1	3111790104216
72000620205699	Argicalm Hot and cold pack Taille / Size 2	3111790104223
72000620305699	Argicalm Hot and cold pack Taille / Size 3	3111790104230
72000620405699	Argicalm Hot and cold pack Taille / Size 4	3111790104247

Nomenclature	Code	Description
EMDN	M9001	Cryotherapy and thermotherapy devices
GMDN	32965	Circulating-fluid thermal therapy system pack, reusable

Destination / Intended purpose	<i>Le dispositif est destiné uniquement au traitement des indications suivantes :</i> -Froid : entorses, foulures, tendinites, migraines, douleurs oculaires, maux de dents, ecchymoses, arthrose, chirurgie maxillo-faciale, chirurgie oculaire -Chaud : douleurs dorsales, contractures/raideurs musculaires et articulaires, crampes, raideur de la nuque, douleurs abdominales <i>The device is intended only for the treatment of the indications listed below:</i> -Cold: sprains, strains, tendinitis, migraine, eye pain, toothache, bruise, arthritis, maxillofacial surgery, eye surgery -Hot: back pain, contractures/muscle and articular stiffness, cramps, stiff neck, abdominal pain
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Sont des dispositifs médicaux de classe I, par application de la règle 1 de l'annexe VIII du règlement (UE) 2017/745

Sont conformes aux exigences de l'annexe I du règlement (UE) 2017/745 applicables aux dispositifs médicaux de classe I

Are class I medical devices by application of the rule 1 of the Annex VIII of the Regulation (EU) 2017/745





Are in conformity with the requirements of Regulation (EU) 2017/745 Annex I relating to Class I medical devices

Références aux normes appliquées par rapport auxquelles la conformité est déclarée – *References of standards applied in relation to which conformity is declared :*

NF EN ISO 13485/A11 : 2021

NF EN ISO 15223-1 : 2021

NF EN ISO 20417 : 2021

Date de marquage CE - *CE marking date* : 2017/11/07

Pour Thuasne - *For Thuasne*:

Nom / *Name* : David Arnould

Fonction / *Function* : Responsable Affaires Réglementaires / Regulatory Affairs Manager

Lieu / *Place* : 27 rue de la Jomayère, 42000 Saint-Etienne – France

Date : 18 juin 2025 | 11:30:56 CEST

Signature :

DocuSigned by:

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