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DICHIARAZIONE DI CONFORMITÀ UE / EU DECLARATION OF CONFORMITY

La presente dichiarazione di conformità UE è rilasciata sotto la responsabilità esclusiva del fabbricante.

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Nome del fabbricante: <i>Manufacturer name:</i>	SYSTEM ASSISTANCE MEDICAL SAS (SYST'AM)	SRN	FR-MF-000003517
Indirizzo del fabbricante: <i>Manufacturer address:</i>	72 ZONE D'ACTIVITE DE CAMPAGNAC 47300 LEDAT - FRANCE Tel. + 33 (0)5 53 40 50 35		
Denominazione del prodotto: <i>Product and trade name:</i>	P161M		
Descrizione del prodotto: <i>Product description:</i>	EMDN / GMDN	UDI-DI di base: <i>Basic UDI-DI :</i>	Codice del prodotto: <i>Product Code:</i>
Materasso da letto. Ausilio per la prevenzione e il trattamento delle piaghe da decubito. Bed mattress. Prevention and treatment aid for pressure sores.	GMDN : 63237 Foam bed mattress EMDN : V080702 NON ACTIVE ANTI-DECUBITUS MEDICAL MATTRESSES	37003686P161MCHI1CK	P161MCPMHI, P161MCPMHI1, P161MCPMHI1NCBX
		37003686P161MSHI1G3	P161MSPMHI, P161MSPMHI190
		37003686P161MTHI1GA	P161MTPMHI, P161MTPMHIBX, P161MTPMHINC, P161MTPMHINCBX
		37003686P161MOHHI1VC	P161MOHPMHI, P161MOHPMHI120, P161MOHPMHI120NC, P161MOHPMHI140, P161MOHPMHI140NC, P161MOHPMHINC,
		37003686P161MOHMF1V3	P161MOHPMHF
		37003686P161MOPPH1HC	P161MOPPMHABX, P161MOPPMHI, P161MOPPMHIBX, P161MOPPMHINC, P161MOPPMHINCBX
		37003686P161MOPPHF1H3	P161MOPPMHABX, P161MOHPMHF, P161MOPPMHF, P161MOPPMHFBX, P161MOPPMHFNC, P161MOPPMHFNCBX
		37003686P161MOPMHI1GP	P161MODPMHI, P161MODPMHI100, P161MODPMHIBX, P161MODPMHINC, P161MODPMHINCBX, P161MOKPMHI160, P161MOKPMHI160NC, P161MOKPMHI170, P161MOKPMHI170NC, P161MOPMHI, P161MOPMHI100, P161MOPMHI100NC, P161MOPMHI110, P161MOPMHI110NC, P161MOPMHI120, P161MOPMHI120NC, P161MOPMHI140, P161MOPMHI140NC, P161MOPMHI160, P161MOPMHI190, P161MOPMHI190NC, P161MOPMHI220, P161MOPMHI220NC, P161MOPMHI70, P161MOPMHI70NC, P161MOPMHI80, P161MOPMHI80NC, P161MOPMHIBX, P161MOPMHINC, P161MOPMHINCBX
		37003686P161MOPMHF1GE	P161MOPMHA, P161MOPMHABX, P161MOPMHANC, P161MOPMHANCBX, P161MOPMHF, P161MOPMHF190, P161MOPMHF190NC, P161MOPMHF80, P161MOPMHF80NC, P161MOPMHFBX, P161MOPMHFNC, P161MOPMHFNCBX
		37003686P161MFHI1D8	P161MFPMHI, P161MFPMHI100NC, P161MFPMHI110NC, P161MFPMHI120, P161MFPMHI120NC, P161MFPMHI80, P161MFPMHI80NC, P161MFPMHINC, P161MFPPMHI, P161MFPPMHINC, P161MFRPMHI, P161MFRPMHINC
37003686P161MFHF1CX	P161MFPM2HF, P161MFPMHF, P161MFPMHF120, P161MFPMHF190, P161MFPMHFBX, P161MFPMHFNC, P161MFPMHFNCBX, P161MFPPMHF		

		37003686P161MFEHF1RB	P161MFEPMHFSTD			
		37003686P161MFEHI1RL	P161MF2RPMHI, P161MF2RPMHINC, P161MFEPMHI, P161MFEPMHINC			
		37003686P161MOEHI1UP	P161MO2RPMHI, P161MO2RPMHINC, P161MOEPMHI, P161MOEPMHINC, P161MORPMHI, P161MORPMHINC			
		37003686P161MOEHF1UE	P161MO2RPMHF, P161MOEPMHF, P161MOEPMHFNC, P161MORPMHF			
		37003686P161MBHI1CC	P161MBPMHI19076, P161MBPMHIS19076			
		37003686P161MBHF1C3	P161MBPMHF19066, P161MBPMHF19076			
Rivestimento di ricambio per materasso antidecubito <i>Replacement cover for pressure sore prevention mattress</i>	GMDN : 32180 Antimicrobial bed mattress cover EMDN : T030502 BED AND STRETCHER HYGIENIC COVERS	37003686HP4XXPM1WS	P451PM, P451PM160, P452PM, P452PM100, P452PM110, P452PM120, P452PM140, P452PM160, P452PM170, P452PM190, P452PM220, P452PM70, P452PM80, P462PM, P471PM, P471PM190			
		37003686HP4XXPF1W5	P452PF, P452PF190, P452PF80, P453PF19066, P453PF19076			
Accessorio per il materasso per la prevenzione delle piaghe da decubito <i>Accessory for pressure sore prevention mattress</i>	GMDN : 44361 Foam-filled chair cushion EMDN : V08030102 NON-ACTIVE ANTI-DECUBITUS MEDICAL CUSHIONS	37003686P161MO212C	P161MO2			
		GMDN : 47477 Air-filled chair cushion EMDN : V08030102 NON-ACTIVE ANTI-DECUBITUS MEDICAL CUSHIONS	37003686P301CHW1YY	P301CR51432HW		
			GMDN : 30034 Bed extension EMDN : V0880 MEDICAL SUPPORT EQUIPEMENT - ACCESSORIES	37003686P101M201T9	P101M20	
				GMDN : 62868 Medical capital equipment storage bag/case EMDN : T0399 PROTECTION DEVICES (EXCLUDING PERSONAL PROTECTIVE EQUIPMENT PPE) - OTHER	37003686PDIV0011LP	PDIV001, PDIV005
					37003686PSAC011F7	PSAC01
37003686PSAC101F9	PSAC10					
Destinazione d'uso: <i>Intended purpose:</i>	Materasso da letto. Ausilio per la prevenzione e il trattamento delle piaghe da decubito. <i>Bed mattress. Prevention and treatment aid for pressure sores.</i>					
Classe di rischio: <i>Class:</i>	I : Classificazione in base all'allegato VIII, capitolo 3, paragrafo 6, regola 1 & 13. <i>I : Classification based on Annex VIII, Chapter 3, Paragraph 6, Rule 1 & 13.</i>					
Organismo notificato: <i>Notified body :</i>	NA					
Specifiche comuni: <i>Common specifications:</i>	NA					

Procedura di valutazione della conformità: Conformity assessment:	Documentazione tecnica conforme agli allegati II e III. Technical documentation according to Annexes II and III
Identificazione del certificato: Reference of certificate :	NA
<p>Il/i prodotto/i a cui si riferisce la presente dichiarazione è/sono conforme/i alle disposizioni del Regolamento (UE) 2017/745 del Parlamento europeo e del Consiglio, del 5 aprile 2017, relativo ai dispositivi medici di classe I ed è/sono conforme/i ad altre legislazioni dell'UE: Regolamento 1007/2011/UE.</p> <p><i>The product(s) to which this declaration refers comply(s) with the provisions of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Class I Medical Devices and comply(s) with other EU legislation: Regulation 1007/2011/UE.</i></p>	
<p>Firmato da e per conto di / Signed by and on behalf of:</p> <p>Sébastien Cinquin Direttore Generale / CEO</p> <div style="display: flex; justify-content: space-between;"> <div data-bbox="359 629 566 750">  <p>SYSTEMAM SAS 72 Zone d'Activité de Campagnac 47300 LEDAT Tél. commerciale : 05 53 40 23 50 Tél. administrative : 05 53 40 50 35 Fax : 05 53 40 29 74 Siret 392 011 920 00015 - ADE 2250A - RC 93 B 05 TVA FR 12 392 011 920</p> </div> <div data-bbox="798 607 973 656"> <p>Lédat Data: 23/01/2025</p> </div> </div>	