Cassina De Pecchi, 03/06/2020

Oggetto: DICHIARAZIONE DI CONFORMITA'

Il sottoscritto Vittorio Perego , in qualità di rappresentante della Ditta importatrice , PVS SpA con sede in Cassina de Pecchi, via Leonardo da Vinci, 18 tel. 029160011, ai fini del MDR 745/2017 del 05/04/2017 sui Dispositivi Medici

DICHIARA che

l'articolo cod. SFI235 SFIGMOMANOMETRO AUTOMATICO DA POLSO è realizzato secondo le normative sopra citate, codice UDI 80563842F, Numero di Repertorio 1909360, CND Z1203020599

Distinti saluti

PVS SPA
Via Leonardo da Vinci 18
20060 Cassina de' Pecchi (Mi)

L' Amminstratore Delegato
Vittorio Perego

Ministero della Salute

Stampa | Scarica il dataset

Elenco dei dispositivi medici

Criteri di ricerca:
Denominazione fabbricante:
Codice fiscale fabbricante:
Partita IVA / VAT number fabbricante:
Codice nazione fabbricante:
Denominazione mandatario:
Codice fiscale mandatario:
Partita IVA / VAT number mandatario:
Codice nazione mandatario:
Tipologia dispositivo:
Identificativo di registrazione attribuito dal sistema BD/RDM: **1909360**
Codice attribuito dal fabbricante:
Nome commerciale e modello:
Classificazione CND:
Descrizione CND:
Normativa:
Classe CE (valida solo per dispositivi medici di classe, impiantabili attivi e IVD):

Elenco dispositivi individuati

Dati aggiornati al:12/06/2022

DISPOSITIVO MEDICO/ASSEMBLATO									FABBRICANTE/ASSEMBLATORE				
TIPOLOGIA DISPOSITIVO	IDENTIFICATIVO DI REGISTRAZIONE BD/RDM	ISCRITTO AL REPERTORIO	CODICE ATTRIBUITO DAL FABBRICANTE/ASSEMBLATORE	NOME COMMERCIALE E MODELLO	CND	NORMATIVA	CLASSE CE	DATA PRIMA PUBBLICAZIONE	DATA FINE IMMISSIONE IN COMMERCIO	RUOLO AZIENDA	DENOMINAZIONE	CODICE FISCALE	PARTITA IVA/VAT NUMBER
Dispositivo	1909360	N	SFI235	SFIGMOMANOMETRO AUTOMATICO DA POLSO	Z1203020599 - MISURATORI NON INVASIVI DELLA PRESSIONE ARTERIOSA - ALTRI	D.L.vo 46/97 attuazione Dir. CE 93/42	IIA - Classe IIa	01/02/2020		FABBRICANTE	SHENZHEN JAMR TECHNOLOGY		
										MANDATARIO	SHANGHAI INTERNATIONAL TRADING CORP. GMBH (HAMBURG)		166892350

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Indietro

DECLARATION OF CONFORMITY
TO COUNCIL DIRECTIVE 93/42/EEC Amended by 2007/47/EC
OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES

MANUFACTURER:
Shenzhen Jamr Technology Co., Ltd
2ND FLOOR, A-BUILDING, NO.2 GUIYUAN ROAD, GUIHUA COMMUNITY, GUANLAN TOWN, LONGHUA NEW DISTRICT, SHENZHEN, CHINA

MEDICAL DEVICE: Blood Pressure Monitor

MODEL NUMBER: W1701,W1101,W1102,W02,W03
CLASSIFICATION - *ANNEX IX, RULE 10*: *CLASS IIA*
CONFORMITY ASSESSMENT ROUTE: *ANNEX V*

WE, THE MANUFACTURER, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC Amended by 2007/47/EC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES; INCLUDING, AT 21 MARCH 2010, THE AMENDMENTS BY COUNCIL DIRECTIVE 2007/47/EC.
ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.
THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.

STANDARDS APPLIED: *SEE ATTACHED LIST OF (HARMONISED - EN) STANDARDS FOR WHICH DOCUMENTED EVIDENCE OF COMPLIANCE CAN BE PROVIDED.*

NOTIFIED BODY:	TÜV SÜD PRODUCT SERVICE GMBH RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY
IDENTIFICATION NUMBER	0123
(EC) CERTIFICATE(S):	*EC CERTIFICATE(S) NUMBER(S) : G2 090084 0007*

EC REP

EUROPEAN REPRESENTATIVE: SHANGHAI INTERNATIONAL HOLDING CORP. GMBH (EUROPE);
Eiffestrasse 80, 20537 Hamburg, Germany;
Tel: +49-40-2513175
Fax:+49-40-255726
E-mail: shholding@hotmail.com

START OF CE-MARKING: *2020.04.30*

PLACE, DATE OF DECLARATION: SHENZHEN *518100，2020-05-01*

SIGNATURE:

NAME: FUSHEGN LUO
POSITION: Management representative

DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC Amended by 2007/47/EC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES

Harmonized Standards List

Product title
Blood Pressure Monitor
Harmonized Standards List.

No	File No.	Edition	File name
1	EN ISO13485	2016	Medical Devices - Quality Management Systems- Requirement for Regulatory Purposes
2	MDD 93/42/EEC (amended by 2007-47-EC)	2007	Medical Device Directive
3	ISO14971	2019	Medical devices - Application of risk management to medical devices
4	IEC 60601-1	2012	Medical electrical equipment-Part1: General requirements for safety and essential performance
5	IEC 60601-1-2	2014	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
6	ISO 10993-1	2018	Biological evaluation of medical device- Part1: Evaluation and testing
7	ISO 10993-5	2009	Biological evaluation of medical device- Part5: Tests for in vitro cytotoxicity
8	ISO 10993-10	2010	Biological evaluation of medical device- Part10: Tests for irritation and delayed-type hypersensitivity
9	IEC 80601-2-30	2013	Medical electrical equipment – Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers.
10	IEC 62366-1	2015	IEC 62366-2007: Medical Devices - Application of Usability Engineering to Medical Devices
11	EN 1041	2013	Information supplied by the manufacture of medical devices
12	MEDDEV2.7.1 REV4	2016	Evaluation of clinical data: A guide for manufacturers and notified bodies
13	IEC 62304	2015	Medical device software-Software life cycle processes

DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC Amended by 2007/47/EC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES

14	IEC 60601-1-11	2015	Medical electrical equipment-Part1-11:General requirements for basic safety and essential performance-Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
15	ISO 14155	2011	Clinical investigation of medical devices for human subjects-Good clinical practice
16	EN ISO15223-1	2012	Medical device-- Symbols to be used with medical device labels, labelling and information to be supplied Part 1: General requirements
17	EN ISO 81060-1	2012	Non-invasive sphygmomanometers - part 1: test methods and requirements for non-automatic measurement types
18	ISO 81060-2	2018	specifies the requirements and methods for the clinical investigation

PLACE, DATE OF DECLARATION:	SHENZHEN *518100，2020-05-01*
SIGNATURE:	
	NAME: FUSHEGN LUO
	POSITION: Management representative