Ministero della Salute

DIREZIONE GENERALE DEI DISPOSITIVI MEDICI E DEL SERVIZIO FARMACEUTICO
UFFICIO 3

DGDMF/3/P/I.5.l.e.1/2024/2228

HAVING REGARD to the Legislative Decree 46/1997;
HAVING REGARD to the Legislative Decree 2022/137;
HAVING REGARD to the article 5 of Regulation (EU) 2017/745 concerning the placing on the market and the putting into service of medical devices;
HAVING REGARD to the article 60 of Regulation (EU) 2017/745 concerning the free sale certificate;
HAVING REGARD to the EU declaration of conformity under Regulation (EU) 2017/745 concerning medical devices mentioned below;
HAVING REGARD to the request ref. 91322-A-31/10/2024, submitted by the company **RIMSA P. LONGONI S.R.L.** with registered office in Via Monterosa, 18 – 20831 Seregno (MB) Italy, VAT N° 00876160961;
HAVING REGARD the Company paid the fees required by Ministerial Decree August 06, 2021;
HAVING REGARD to the official deeds;

IT IS ATTESTED

that, the Company **RIMSA P. LONGONI S.R.L.** with registered office in Via Monterosa, 18 – 20831 Seregno (MB) Italy, according to the procedures provided by the Regulation (EU) 2017/745, is the manufacturer and has marked CE as medical devices the following medical device:

Ref.	Code	Basic-UDI DI
PENTA63N	PENTA63NSO	++B880LUMINAIREPM
	PENTA63N+63N	
	PENTA63N+30N	
PENTA30N	PENTA30NPI	
	PENTA30NSO	
	PENTA30NPA	
	PENTA30N+30N	
PENTA12	PENTA12PI	
	PENTA12SO	
	PENTA12PA	
	PENTA12+12	
PENTA28	PENTA28PI	
	PENTA28SO	
	PENTA28PA	
	PENTA28+28	

SAT-LED	SATPIN-LED	++B880LUMINAIREPM
	SATSON-LED	
	SATPAN-LED	
	SATSONX2-LED	
PENTA30E	PENTA30EPI	
	PENTA30ESO	
	PENTA30EPA	
	PENTA30E+30E	
UNICA520	UNICA520PA	
	UNICA520PI	
	UNICA520SO	
	UNICA520+520	
UNICA860	UNICA860PI	
	UNICA860SO	
	UNICA860+520	
	UNICA860+860	
U29	U29PA	
	U29PI	
	U29SO	
	U29+29	
PRIMA-FIX	PRIMA-FIX	
PRIMA-FLEX	PRIMA-FLEX	
ALFA-FIX	ALFA-FIX	
ALFA-FLEX	ALFA-FLEX	
L88-LED-M	L88-LED-M	
QUATTRO	QUATTROSO	
	QUATTROPA	
	QUATTROPI	
	QUATTROSOX2	
PENTA30EL	PENTA30ELPI	
	PENTA30ELSO	
	PENTA30ELPA	
	PENTA30EL+30EL	

The above mentioned products, according to the article 5 of Regulation (EU) 2017/745, can freely circulate and can be placed on the market in Italy and all over the European Union.
This document has been issued in original version upon request of the manufacturer in order to export medical devices to **Countries outside European Union**.
It is not allowed any reproduction or publication of this document by paper, press, electronic base or websites.
It is only allowed to show or to delivery it, upon request of the customs or Health Competent Authorities of the importing country.

The Health Manager
Dott. Marco Musella

RB