



Ministero della Salute

DIREZIONE GENERALE DEI DISPOSITIVI MEDICI E DEL SERVIZIO FARMACEUTICO
UFFICIO III EX DGFD

DGDMF/III/P/I.5.1.e.1/2016/223

HAVING REGARD to Directive 93/42/EEC concerning medical devices;

HAVING REGARD to the Legislative Decree n. 46/97 and its following amendments implementing Directive 93/42 EEC;

HAVING REGARD to the request ref. 0007335-A-12/02/2016 submitted by the Company **RIMSA P. LONGONI S.r.l.** located in 20831 Seregno (MB), Italy, via Monterosa 18/20/22, VAT N 00876160961.

WHEREAS the Company paid the fees required by Ministerial Decree August 7th, 2012;

HAVING REGARD to the official deeds:

IT IS ATTESTED

that, according to the Directive 93/42/EEC, the Company **RIMSA P. LONGONI S.r.l.** located in 20831 Seregno (MB), via Monterosa 18/20/22, Italy, is the manufacturer and has marked CE as medical devices the following products:

“D600 (code: D600), D1200 (code: D1200), D1000 (code: D1000), D400 PI (code: D400PI), D400 SO (code: D400SO), D400 PA (code: D400PA), D400X2 (code: D400X2), PENTALED 63N SO (code: PENTA63NSO), PENTALED 63N PI (code: PENTA63NPI), PENTALED 63N+63N (code: PENTA63N+63N), PENTALED 63N+30N (code: PENTA63N+30N), PENTALED 30N PI (code: PENTA30NPI), PENTALED 30N SO (code: PENTA30NSO), PENTALED 30N PA (code: PENTA30NPA), PENTALED 30N+30N (code: PENTA30N+30N), PENTALED 12 PI (code: PENTA12PI), PENTALED 12 SO (code: PENTA12SO), PENTALED 12 PA (code: PENTA12PA), PENTALED 12+12 (code: PENTA12+12), PENTALED 28 PI (code: PENTA28PI), PENTALED 28 SO (code: PENTA28SO), PENTALED 28 PA (code: PENTA28PA), PENTALED 28+28 (code: PENTA28+28), TRIS-LED PI (code: TRISPI-LED), TRIS-LED SO (code: TRISSO-LED), TRIS-LED PA (code: TRISPA-LED), TRIS-LED X2 (code: TRISSOX2-LED), SATURNO-LED PI (code: SATPI-LED), SATURNO-LED SO (code: SATSO-LED), SATURNO-LED PA (code: SATPA-LED), PENTALED 81 PI (code: PENTA81PI), PENTALED 81 SO (code: PENTA81SO), PENTALED 81+81 (code: PENTA81+81), PENTALED 81+30E (code: PENTA81+30E), PENTALED 105 SO (code: PENTA105SO), PENTALED 105+105 (code: PENTA105+105), PENTALED 105+81 (code: PENTA105+81), PENTALED 105+30E (code: PENTA105+30E), PENTALED 30E PI (code: PENTA30EPI), PENTALED 30E SO (code: PENTA30ESO), PENTALED 30E PA (code: PENTA30EPA), PENTALED 30E+30E (code: PENTA30E+30E), PRIMALED (code: PRIMA), PRIMALED-FLEX (code: PRIMAFLEX), PRIMALED SO (code: PRIMASO), A06 (code: A06), ALFA-LED (code: ALFA-LED), L88 (code: L88)”

The above mentioned products, according to the art. 4 of Directive 93/42/EEC, can freely circulate and can be placed on the market in Italy and all over the European Union.

This document has been issued in a unique 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 Office Manager
Dr. Annamaria DONATO

CS