DECLARATION OF CONFORMITY

CE

The Manufacturer

KSP ITALIA

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ENSURES AND DECLARES that the following products

Catalogue Name A 5012 BED ONE CRANK
Italian Ministry Repertory Number 27724

Class I[1] Medical Devices, meet the provisions of the Directive 93/42/CE and subsequent amendments which apply, having the manufacturer followed the procedure referred to in Annex VII of the afore mentioned Directive, and being the Medical Devices registered in the Ministry of Health Repertory of Medical Devices.

The Manufacturer declares furthermore that all the devices are designed and manufactured according to the following standards:

UNI EN 980 UNI EN 1041 UNI EN 14971

Pb lead-free RoHS

The products are free of lead, mercury, cadmium and Hexavalent chromium or their compounds, PBB o PBDE, According to Directive 2002/95/EC (RoHS, restriction of the use of certain hazardous substances in electrical and electronic equipment).

All the products are manufactured according to the requirements issued by the current reregulation with respect to safety and health in the workplace being the manufacturer OHSAS 18001 Certified, certificate number 113121 – 2012 – AHSO – ITA – ACCREDIA, Notified Body DET NORSKE VERITAS (DNV)

Neither parts of the devices nor a device itself are intended to administer and/or remove medicines, body liquids or other substances to or from the body, or devices intended for transport and storage of such body fluids or substances, contain phthalates which are classified as carcinogenic, mutagenic or toxic to reproduction, of category 1 or 2, in accordance with Annex I to Directive 67/548/EEC,

The Medical Devices do not incorporates, as an integral part, a medicinal product derived from human blood or human plasma and " human blood derivative' described at paragraph 7.4 annex I Directive 2007/47/CE, and the Devices are not manufactured utilizing tissues of animal origin as referred to in Commission Directive 2003/32/EC

Bevagna 22 / 03 / 13

Person authorized to legally bind the company
CEO
Claudio Emanuelli

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[1] According to annex IX of the Medical Devices Directive