

EC Certificate

EC Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60090366 0001

Report No.: 28106151 001

Manufacturer: Colonplus Equipments & Speculums, S.L.
c/Portuetxe, 13 – 1.C
20018 San Sebastian (Guipúzcoa)
Spain

Scope: Medical Devices for colon cleaning.

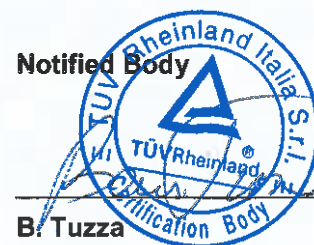
COLONKIT LARGE (COLONKIT GRANDE)
COLONKIT SMALL (COLONKIT PEQUEÑO)
COLONKIT WITH STOP COLLAR (COLONKIT (TOPE))

Date of Expiry: 25/11/2018

The Notified Body hereby declares that the requirements of annex V of the Directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned Directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to annex III is required.

Pogliano Milanese (MI)

26/11/2013



TÜV Rheinland Italia S.r.l. - Via Mattei, 3 - 20010 - Pogliano Milanese (MI)
Accreditated by Ministero della Salute and by Ministero dello Sviluppo Economico
with decree of January 09th, 2013 (G.U. n. 32 February 07th 2013)

Notified under No. **1936** to the EC Commission



The CE marking may be used if all relevant and effective EC Directives are complied with

