

EC Certificate

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

Registration No.: DD 60076222 0001

Report No.: 28104964 001

Manufacturer: TRANSCENDENCIAS COMERCIALES, S.L.
Parque Empresarial Zuatzu c/Zubiberri, 31 Bajo 1
20018 Edificio Urumea – San Sebastian
Spain

Scope: Medical Devices for colon cleaning.
(See the attachment for models designation)


Date of Expiry: 04/04/2017

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)

05/04/2012

Notified Body



B. Tuzza

TÜV Rheinland Italia S.r.l. - Via Mattei, 10 - 20010 - Pogliano Milanese (MI)
Accreditated by Ministero della Salute and by Ministero dello Sviluppo Economico
with decree of June 26th, 2007 (G.U. n. 168 del 21 Luglio 2007)

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



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



TÜV Rheinland Italia S.r.l.

Via Mattei, 3 - 20010 - Pogliano Milanese (MI)



**Attachment to
the certificate:**

DD 60076222 0001

Report No.:

28104964 -001

Manufacturer:

**TRANSCENDENCIAS COMERCIALES, S.L.
Parque Empresarial Zuatzu c/Zubiberri, 31 Bajo 1
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Spain**

Scope:

Models: HC-1
HC-1 Classic
HC-2000
HC-2000 Classic
HC-3000

**Accessories for Colon cleaning equipment
(See report no. 28105771-001 issued on 03/04/2013)**

Models: Large Hydrokit;
Small Hydrokit;
Hydrokit with limiter;
Segmented Hose/Hydrokit with limiter;
Gravity 10 mm inflow/ Hydrokit with limiter;
Segmented Hose/Large Hydrokit

Notified Body

Pogliano Milanese

10/04/2013

