

EC Certificate

**Directive 93/42/EEC Annex II excluding (4)
Full Quality Assurance System
Medical Devices**

Registration No.: OH 69249239 0001

Report No.: 28226657 001

Manufacturer: **TAISSIS Concept S.R.L.**
17, Ion Ticaloiu Street,
115100 Campulung
Romania

Products: See attachment for complete product list

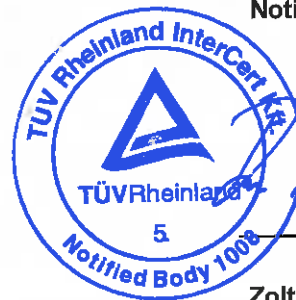
The Notified Body audited the quality system and certifies that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, Article 5 of the aforementioned directive. For placing on the market of Class III devices covered by this certificate, an EC design-examination certificate according to Annex II (4) is required.

Issue Date: 2015-04-13

Effective Date: 2015-04-13

Expiry Date: 2019-07-28

Notified Body



Zoltán Ambrus MD.

Page: 1 / 3

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TÜV Rheinland InterCert Kft. is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 1008.

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Products:

GMDN code	REF, Name
11325	Sterile paraffin dressing
11325	Sterile impregnated compresses with ointment, ointment
34864	Impregnated dressings with rivanol
17428	Sterile polyurethane film
33961	Sterile surgical sets for single use
33961	Sterile surgical instruments for single use
35099	Sterile cardiology kits
37276	Sterile transplant organs kits
47605	Cleansing/ irrigation solutions for gynecology
56700	Cleansing / irrigation solutions for Ear, Nose and Throat
43186	Sterile hydrocolloid impregnated dressings, adhesive and non-adhesive
44970	Sterile polyurethane dressings, adhesive and non-adhesive
46854	Sterile polyurethane dressings with silicone

Budapest, 2015-04-13

Page: 2 / 3



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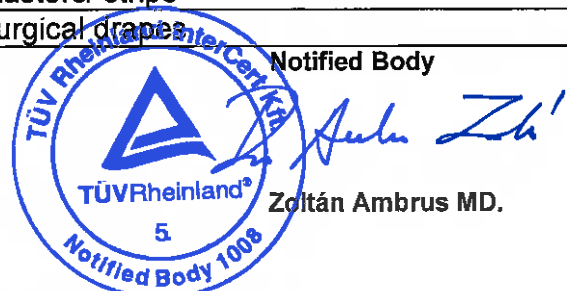
Products:	GMDN code	REF, Name
	46854	Sterile polyurethane with silicone, adhesive and non-adhesive , impregnated dressings with silicone and silicone gel
	43186	Sterile polyurethane hydrocolloid dressings
	47694	Sterile hydrogel solutions/ impregnated compresses with hydrogel, unidose, spray
	40425	Sterile cleansing/ irrigation solutions for wounds
	47764	Sterile hydrogels for wound debridement
	43186	Sterile hydrocolloid dressings
	46556	Cold therapy medical devices. gel, solution, impregnated dressings, impregnated bandages

For the following medical devices the scope covers only the aspects of manufacture concerned with securing and maintaining sterile condition

33961	Sterile surgical drapes kits
32293	Sterile surgical gowns
34970	Sterile gauze and non-woven compresses
34864	Sterile plasters/ strips
33961	Sterile surgical drapes

Budapest, 2015-04-13

Page: 3 / 3



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