

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

Registration No.: OD 69252567 0001

Replaces certificate: OD 69246606 0001

Report No.: 28211468 004

Manufacturer: 3 Teks Tekstil Gida Ithalat Ihracat San.Tic.LTD.STI
2.Organize Sanayi Bölgesi, No:1, Baspınar,
27650 Gaziantep – TURKEY

Products:

GMDN code	REF, Name
17881	EVLA SET
17881	PLDD SET
17881	EVA SET

(See attachment for complete product list)

The Notified Body audited the quality system and certifies 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, Article 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.

Issue Date: 2016-05-10

Notified Body

Effective Date: 2016-05-10

Expiry Date: 2019-05-08



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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.

ATTACHMENT

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 Sanayi Bölgesi, No:1, Baspinar,

Products: 27650 Gaziantep – TURKEY

GMDN code	REF, Name
35833	Infusion Set Standart
36530	Peristaltic Pump Infusion Sets
17569	Sclerotherapy Liquid Infussion Sets
44545	Y- Connector
32172	Stopcoks
32172	Manifolds
32337	Puncture/ Introducer Needles
36177	Insertion Tools
15286	Control Syringes
12170	Pressure Line
12170	Extension Line
16545	Manifold Kit
10678	Percutaneous Introducer Set (Introducer Sheath)
44545	Y-Connector Kit
11969	Tubing Sets
16163	Cardioplegia Perfusion Sets
31296	Tubes

Budapest, 2016-05-10

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Products:

GMDN code	REF, Name
38568	Connectors
38568	Connectors
17580	Arterial Filter
15649	Oxygen Filter
17580	Pre-bypass Filter
17501	Spikes (Vented, Non-vented)
17501	Drip Chamber
34894	Yankauer Cannula
18018	Check Valve
13803	Stopcock

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Products:

GMDN code	REF, Name
17807	Optical Fiber
34099	Vein Valves and Sets
36177	Torquer
17541	Inflation Device
35531	Disposable Surgical Drapes
35091	Disposable Surgical Gowns

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