



C E R T I F I C A T E

Production Quality Assurance for Medical Devices

Technical file of the company mentioned below has been inspected and audit has been completed successfully. MDD 93/42/EEC Directive of Medical Devices Annex II - OBL and ISO 13485:2012 has been taken as references for these processes.

Company Name : Accutaş Sağlık Medikal Uluslararası Ticaret Turizm Gıda Veterinerlik Danışmanlık A.Ş.

Company Address : Demetevler Mah. 365. Sok. No:11/2 Yenimahalle ANKARA / TÜRKİYE

Related Directives and Annex : MDD 93/42/EEC Medical Devices Directive - Annex II - OBL (Class IIa - Sterile)

Product : Hydrophilic urinary catheter kit, Hydrophilic urinary catheter with water sachet, Nelaton catheter, Nelaton feeding catheter, Nelaton aspiration catheter, Hydrophilic urinary catheter, Neo-cath KIT urinary catheter kit with gel sachet, Neo-cath urinary catheter with gel sachet, Hydro touch water soluble lubricating hydrophilic instillation urinary catheter (with/without water sachet and kit), Antibacterial hydrophilic urinary catheter (with/without water sachet and kit), Extension line, Perfusion line, Infusion line, Pressure line, T connector line, Subrapubic puncture set, Subrapubic exchange set, Silicone foley catheter, Silicione foley catheter kit, Sterile inhalation water, Sterile circumcission device, Sterile circumcission kit

Certificate Number : A.2013.106.1693

Notified Body Number : 2292

Initial Assessment Date : 12.12.2012

Registration Date : 07.02.2013

Reissue Date/No : -

Expiry Date : 06.02.2018


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NB 2292



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