TÜVRheinland®

APPROVAL

EC Directive 93/42/EEC Annex V, Article 3
Quality Assurance System Production

Registration No.: DD 60035086 0001

Report No.: 20090912 001

Manufacturer:
Overtoom Ltd.
3rd Floor, Ulysses House
Foley Street
DUBLIN 1
Ireland

Scope: Manufacturing of urology balloon catheters

Date of Expiry: 10.03.2015

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex V, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex V, Article 4 of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Date 27.01.2011

Dr. J. Breder

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Accredited by Zentralstelle der Länder für Sicherheitstechnik (ZLS) and
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG).

Notified under No. 0197 to the EC Commission.

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