TYTEX®

MAKING HEALTHCARE MORE HUMAN

PRODUCT SAFETY POLICY

TYTEX will be recognized as a leading global partner providing value within global niche markets for medical textile products and thus contribute to improving the safety of our products and quality of life for users.

We will do this by:

- Ensuring that safety and product hygiene is top priority by maintaining employee training and good housekeeping practices at each of our facilities. To ensure safety and hygiene of our products, Tytex has implemented numerous preventative systems and instructions for our employees and suppliers both internally and externally.
- Maintaining a documented management system, which conforms to the defined scope of ISO 13485:2012, ISO 9001:2008, ISO 14001:2004, 21 CFR 820 (FDA) and Council Directive 93/42/EEC for Medical Devices.
- Measuring and benchmarking our customer's satisfaction in order to ensure that all product safety issues that may be highlighted are dealt with in a timely manner and therefore ensuring a process of continual improvement, including the establishment of appropriate Product safety objectives and targets.
- Committing to comply with applicable regulatory, legislative and other equirements.
- Using the input of employees, customers, shareholders, authorities and other interested parties/stakeholders to improve the safety of our products and processes and to minimize any adverse health and safety impacts.
- Ensuring that our Product Safety Policy is communicated and understood by all Tytex employees and subcontractors and is made available to the public upon request.
- Continuously caring for our employees through involvement, education and personal development.

This policy is supported and periodically reviewed for continuing suitability, adequacy and effectiveness by Tytex Management. Management shall commit the necessary resources to ensure that compliance with the above is achievable throughout Tytex.

The CEO of Tytex is responsible for endorsing the Tytex Product Safety Policy. Each Tytex subsidiary is responsible for posting endorsed copies of the current policy throughout their facility.

January 30th 2014
Date

Tytex CEO

1.0 ADDENDA:

Ideas for the improvement and/or revision of this WIP are encouraged from all who work with it. Contact your department manager/supervisor or Quality & Environmental Manager.

2.0 REVISION HISTORY:

REV.	DATE	DESCRIPTION OF CHANGE	BY
1.0	27.11.06	Initial release of ISO 13485:2003 work instruction.	Q&E Group
1.1	30.05.07	To reflect the stop of EMAS Statements in Tytex Group.	KIR
1.2	06.02.07	Added - OHSAS 18001:2007 (where applicable).	PDH
1.3	15.04.09	To reflect the ISO 9001:2008 implementation	KIR
1.4	01.03.11	Removed Group in Tytex Group and OHSAS. New CEO	KIR
1.5	08.02.12	Added Council Directive 93/42/EEC for Medical Devices.	KIR
1.6	12.12.12	Added 21 CFR 820 (FDA)	KIR
1.7	30.01.14	Corrected ISO 13485 from 2003 to 2012	KIR