



Customer Care



Technical Information

Providing Dedicated Technical Support



vygon@vygon.co.uk

www.vygon.co.uk

Technical Information



We have two main Technical Sites, Aachen, Germany & Ecoen, France. German technical development concentrates on 'high tech' products such as paediatric & neonatal products and devices used for monitoring or stimulation.

The French technical team work on most other Vygon products.

Both sites have CAD drawing offices, development and pilot plant laboratories and raw material analysis laboratories. Additionally both sites have close working relationships with local hospitals for any clinical development.

All Vygon facilities are ISO9000 & ISO13485 certified. Additionally both main facilities have EO sterilisation on site and are certified to EN550.

All products manufactured or distributed by Vygon are CE marked where required and as such meet the requirement of the Medical Devices Directive 93/42/EEC. Manufacturing sites are audited for Directive compliance. In Germany we use TUV as our Notified Body, and in other sites GMED are employed.

In house, quality control procedures vary according to the product. A large number of products are controlled in line by automated equipment with separating reject systems in place. Some products are individually inspected by hand where the need is deemed necessary and all products are inspected in a Lot sampling basis according to standard AQL type procedures.

Technical or Quality personnel are all selected based on experience and qualification. We have a number of pharmacists, industrial and plastics chemists and engineers and a number of technicians. In total we have 47 staff in the Quality Assurance and Quality Control Departments, and 46 staff in Technical Support and Research and Development. Final responsibility for all aspects of quality rests with the appropriate Quality and Regulatory Directors in Germany and France.

Technical Support

Technical Support is offered during normal working hours (9am-5pm) through our experienced, dedicated team, with cover generally available from 8am through to 7pm weekdays.

The department handles technical enquiries, procedural advice, regulatory device issues and any problems that may occur with Vygon products.

Customer enquires will be acknowledged within eight working hours of receipt when directed through Vygon switchboard. Direct dial enquires will be acknowledged within four hours of pickup.

All enquiries will be resolved within seven working days of all necessary information being provided.

We also have a 24-hour answering machine service and an Emergency telephone contact.



Gastrostomy Service & Support

Vygon (UK) Ltd are the only company who have an investigative laboratory in the UK for tubes, offering a 24 hour turnaround response.

85% of the population worldwide that have a gastrostomy button, use a MIC Gastrostomy Button and Extension Line. Vygon (UK) Ltd hold the best safety record for this type of product.

Technical Support Contact Information

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CERTIFICAT
CERTIFICATE OF REGISTRATION
CERTIFICADO
N° 9566 rev. 3

Le LNE certifie que le système de management de la qualité développé par
LNE certifies that the quality management system developed by
LNE certifica que el sistema de gestión de la calidad desarrollado por

VYGON S.A.
5-11 rue Adeline,
95440 ECOUEN FRA

pour les activités / for the activities / para las actividades

Conception, fabrication et commercialisation de dispositifs médicaux et accessoires, stériles et non stériles, à usage unique. Validation et contrôle de routine de la stérilisation à l'oxyde d'éthylène de dispositifs médicaux selon l'EN 550. Voir addendum.

Design, manufacturing and sales of sterile or no sterile single use medical devices and accessories. Validation and routine control for ethylene oxide sterilization of medical devices according to EN 550. See addendum.

Diseño, fabricación y comercialización de dispositivos médicos y accesorios, estériles y no estériles, descartables. Validación y control de rutina de la esterilización al óxido de etileno de dispositivos médicos según el EN 550. Ver Anexo.

réalisées sur le(s) site(s) performed on the location(s) / que se realizan en

Voir addendum / See addendum / Ver anexo

est conforme aux exigences des normes internationales
complies with the requirements of the international standards
es conforme a las exigencias de las normas internacionales

ISO 9001 : 2000

Début de validité / Effective date / Fecha efectiva : May 10th, 2009 (included)
Valable jusqu'au / Expiry date / Fecha de expiración : May 9th, 2012 (included)
Etabli le / Issued on / Fecha de preparación : May 6th, 2009



On behalf of the Deputy Director
Thierry THOMAS
G-MED Certification Division Manager
Responsable de la División Certificación G-Med



LNE N° 9566- N° 3
Ce certificat est délivré selon les règles de certification G-MED / This certificate is issued according to the rules of G-MED certification
LNE/G-MED Organisme notifié pour les Dispositifs Médicaux / LNE/G-MED Notified Body for Medical Devices
N° 4-0038
Portée disponible sur www.lne.fr
Renouvele le certificat 9566-2

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