



global assurance

## Report of Conformity

Product: Non-woven caps, Non-woven face masks, Non-woven gowns, Non-woven coveralls, Non-woven surgical gowns, Non-woven shoe covers, Under pads, PE/CPE shoe covers and gowns

Type: Various

Applicant: Halley Medical Supplies Ltd

Address: 1400 Coventry Road, South Yardley, Birmingham, B25 8 AE, UK

**The submitted sample of the above product has been tested for CE marking according to the related European Directives 93/42/EEC Medical Device Directive (including 2007/47/EC)**

*Standard(s) used for showing compliance with the essential requirements in the specified directive(s):*

Standard(s): EN ISO 14971:2009, EN ISO 10993-1:2009, EN 1041:2008, EN ISO 10993-5:2009, EN ISO 10993-10:2009, EN 980:2008, EN ISO 14155-1:2009, EN ISO 14155-2:2009, EN 13795-1:2002+A1:2009, EN ISO 22610:2006, EN 13795-2:2004+A1:2009, EN 13795-3:2006+A1:2009

The technical documentation of the listed devices is in conformity with the requirements.  
The test report is the annex of this report and we suggested they could be used together.  
The applicant may affix the CE marking as shown below to the product.

Report No. **01823**  
Date: **22 Aug 2011**  
Expiry date: **21 Aug 2016**

General Manager (Signature)

