# EC Declaration of Product Conformity

The manufacturer established in the community;

**BM Polyco Ltd**
**Crown Road**
**Enfield**
**EN1 1TX**
**United Kingdom**

Certified to ISO 9001 & ISO 13485

declares that the new Medical Device described hereafter

# FINEX STERILE

Sterile, powder-free, natural rubber, examination glove

is in conformity with the provisions of Council Directive 93/42/EEC, subsequent amendments including Annex I (Essential Requirements) and EN455 parts 1-4.

this product is a Class I sterile device and is certified by the Notified Body, LRQA UK, 1 Trinity Park, Bickenhill Lane, Birmingham, B37 7ES, UK (Notified Body No. 0088) who have assessed BM Polyco Ltd against the requirements of ISO 13485 and EC Directive 93/42/EEC Annex V (certificate no. LRQ0925589/B).

CE 0088

## Product Information

| Size | Small | Medium | Large |
|---|---|---|---|
| Code | LES100/01 | LES100/02 | LES100/03 |

**Glove Care:** Store below 25°C away from direct sunlight
**Freedom from holes:** AQL 1.5
**Physical properties:** 6N minimum
**Latex protein:** <50μg/g

This product contains natural rubber latex, which may cause allergic reactions.
This product contains low levels of residual chemical accelerators, which may cause allergic reactions.

Done at Enfield, 17/11/15

Bernard Garvey
Technology Director