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

Issue No. 9 Model Ref. Finex Sterile Prepared at Enfield on 17/11/15