

"EC" DECLARATION OF CONFORMITY



Nunn Brook Road, Huthwaite, Sutton-in-Ashfield, Nottinghamshire. NG17 2HU

declare on our own responsibility that product(s)

091253673 081542919 **AQUAFLEX MULTILINGUAL**
091323435 **AQUAFLEX SPARE CONES**
091323443 **AQUAFLEX SPARE WEIGHTS**

Comply with the assessment criteria of Council's Directives:
-93/42/EEC, as amended by all subsequent Directives including 2007/47/EC.
and also comply with:

- BS EN ISO 12182 - Assistive products for persons with disability.
- BS EN ISO 14971 - Application of Risk Management for Medical Devices.

and the quality system of the manufacturer is in conformity with the following standards :

BS EN ISO 9001:2015
BS EN ISO 13485 :2016

Patterson Medical Certificate N° FM36058 originally registered by BSI on 24/01/1997
Current Certificate N° LRQ4006200/C registered by LRQA 11/09/2013, expires March
2022

Certificate for approval of full Quality Assurance System

Additional information: Product file No 271 Aquaflex
Directive classification: Class 1, Non-sterile
Intended use: Pelvic Muscle floor Exerciser (weighted vaginal cones)

Performance Health,
Nunn Brook Road, Huthwaite,
Sutton-in-Ashfield,
Notts. NG17 2HU
04.03.2019





Louise Jones
Quality and Compliance Manager