Maxxcare bv
Koetserstraat 10
1531 NX Wormer

Tel 072 5322204
Fax 072 5322803

info@maxxcare.nl
www.maxxcare.nl

Declaration of conformity

for Medical Devices

Maxxcare
Koetserstraat 10
1531 NX Wormer
THE NETHERLANDS

We hereby declare that the Class I products specified below meet the relevant provisions of the European Medical Device Directive 93/42/EEC. The conformity assessment procedure followed is set out in Annex VII (Declaration of Conformity) of the Medical Device Directive. This Declaration of Conformity covers the CE marked products specified on the attached product list.

General applicable directives:

- Besluit medische hulpmiddelen van 30 maart 1995 in het Staatsblad 243
- Medical Device Directives: Council Directive 93/42/EEC concerning medical devices (MDD 93/42/EEC).
- Directive Packaging and waste: 94/62/EG.

Standards: (latest version)

- Harmonised Standards (published in the Official Journal of the European Communities) applicable to these products are:
  EN 12182 and subsequent product standards;
  Risk Analysis carried out according to EN 14971;
  Guidelines Vigilance System MEDDEV 2.12/1;
  Guidelines to the Classification MEDDEV 10/93.

Details of the products are laid down in the Technical File, which is present at the above mentioned address. The Technical File complies with the requirements of the Directive MDD 93/42/EEC.

Date: 01-01-2012

M. Rogmans
General Manager

Date: 01-01-2012

R.N. Winkel
QA Manager

Maxxcare bv
Koetserstraat 10
1531 NX Wormer

Tel 072 5322204
Fax 072 5322803

info@maxxcare.nl
www.maxxcare.nl

Product List

Annex to Declaration of Conformity
For products of the category: Class I

Models:

Name of the product	Available variants (sizes in cm)
Heel Protector	Standard size (ST) & Xlarge size (XL)

Change(s):

01-01-2012	New document	Rev. 00