

Evidence of conformity for the Product (group)

Product (group):

BackJoy



Judicial Status:

Class I acc. EWG 93/42/MPG

Manufacturer (judicial):

BackJoy Europe BV

Laan van Waalhaven 175
2497GK The Hague

The Netherlands

15-7-2012
Date


Responsible person

Masterfile

4. List of applicable standards

For our product, the following regulations come to bear:

List of applicable standards and regulations:

RL 93/42 EWG	(medical devices)	X
RL 2007/47 EWG	latest addition to EEC 93/42	X
EN 14971(2007)	(Risk-management)	X
MEDDEV 2.7.1 (2003)	(clinical evaluation)	X
EN 980 (2008)	(Labeling of medical devices)	X
EN 1041 (2008)	(Information supplied by the manufacturer of medical devices)	X

X = applicable

12. Ability - type examination, material certificates, certificates suppliers

The manufacturer must undertake in the context of the Delimitation / supply agreement, to qualify the used materials. (see chapter 1)

The Product is qualified to receive the CE Mark.