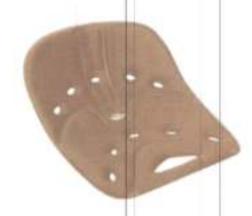


### Masterfile

Evidence of conformity for the Product (group)

Product (group):







Judicial Status:

Class I acc. EWG 93/42/MPG

Manufacturer (judicial):

BackJoy Europe BV

Laan van Waalhaven 175 2497GK The Hague

The Netherlands

15-7-7013

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



# Masterfile 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.