

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

<b>Masterfile</b>
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**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.