



Declaration of Conformity

ArjoHuntleigh AB, Verkstadsvägen 5, 241 38 ESLÖV, Sweden, as the manufacturer of the following Medical Devices, declare conformity with the applicable provisions of Directive 93/42/EEC of 14 June 1993, concerning medical devices, by Annex II and applicable sections of the standards listed.

This declaration covers the devices listed below:-

Device Family Name:	PREVENTION/ MANAGEMENT OF ALL GRADES OF PRESSURE ULCER ALPHA ACTIVE 3/ HM648
GMDN Number and Term:	47478 Alternating-pressure bed mattress overlay system
Risk Class and Rule:	Class IIa/ Rule 9
Notified Body Name and Number	 BSI 0086 0086

Name	Position	Signature	Date
Julie Nunn	Supply Chain Quality Director		23 Oct 2012

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Product Model Numbers - Pump

Product Code	Model Number	Description
648301	648301	ALPHA ACTIVE 3 PUMP – UK
648304	648304	ALPHA ACTIVE 3 PUMP – GERMANY
648305	648305	ALPHA ACTIVE 3 PUMP – EURO
648309AU	648309AU	ALPHA ACTIVE 3 PUMP – AUSTRALIA

Product Model Numbers – Mattress

Product Code	Model Number	Description
648321	648321	ALPHA ACTIVE 3 OVERLAY 90CM
648323	648323	ALPHA ACTIVE 3 OVERLAY 85CM
648325	648325	ALPHA ACTIVE 3 OVERLAY 85CM PU