semeda®
MEDIZINISCHE INSTRUMENTE

EC-Declaration of Conformity
acc. to Attachment VII of the EC Regulations 93/42/EEC

We, the company

Semeda Medical Instruments e.K.
Bergstraße 8
29389 Bad Bodenteich
Germany

with sole responsibility
as producers in accordance to EC regulation 93/42/EEC, Section 1, § 2f,
declare that
the products as described in the product act PA 003 BETA-Flex Foot Abduction Splint

BETA-Flex Brace
Foot Abduction Brace

were construed so as to singly conform to the requirements of EC regulation 93/42/EEC.

Medical product class: (in acc. with Attachment IX of the EC-Reg. 93/42/EEC)	I Rule 1
Applied harmonised norms:	see Product file PA 003, § 5
Evaluation process of conformity:	Attachment VII, § 1-4 of the EC Reg. 93/42/EEC

Bad Bodenteich, 07.08.14
Place, Date

Harald Kuijus, Business Manager