INTERESPUMA
INDÚSTRIAS DE POLIURETANOS, LDA

Rua da Solidariedade
Zona Industrial de Alféloas - Apartado 92
3781-907 Anadia Portugal
tel: (351) 231 511 022 fax: (351) 231 511 845

Orthia®

Orthia

EC DECLARATION OF CONFORMITY

(Class I Medical Devices)

Interespuma - Indústrias de Poliuretanos, Lda., with headquarters in Zona Industrial de Alféloas, Anadia,

DECLARES:

That the medical devices described below, meet the specifications required by the Annex I of the European Community Directive 93/42/EEC of 14 June, which apply to it. Therefore it does not compromises the clinical condition, health or safety of the patients, users or other persons, when used under the conditions and for the intended purposes, considering that the eventual risks associated with the use are acceptable when compared with the benefits provided to the patient and are compatible with a high degree of health protection and safety.

CLASSIFICATION: ☑ Class I (Rule 1)

COMPROMISES TO:

- Create and maintain an updated systematic analysis procedure of the acquired experience in the post-production phase of the devices.
- Develop appropriated means to apply any necessary corrective actions, taking in account the nature and risks related to the products and notify the competent authorities about its incidents, such as:
  - ✓ Any malfunction, damage or deterioration in the performance of the device, as well as any inaccuracy, omission or insufficiency in the labeling or the instructions for use of a device, that might cause or might have led to the death or a severe deterioration in the state of health of the patient, user or other;
  - ✓ Any indirect damage, following a incorrect medical decision, related to the medical device, when used according with the instructions of use provided by the manufacture;
  - ✓ Any technical or medical reason connected with the characteristics or functional behavior of the device that, for the referred reasons in the previous points, might has led to safety corrective actions of devices of the same type by the manufacturer;
  - ✓ Other information that the experience proves that should be notified.
- To elaborate technical documentation and keep it updated, including this declaration, at competent authority disposal for inspection over five years after the last date of manufacture of the medical device.

Sociedade por Quotas - Matriculada na C.R.C. Anadia sob o Nº 1302/930205 - Capital Social 89.783,63 Euros - Cont. Nº 502 501 685

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PRODUCT TYPE	MODEL
ORTHOPEDIC PILLOWS	COMFORT, COMFORT PLUS, CLASSIC, EVOLUTION
CUSHIONS	Round, Square, Square with Hole, Horseshoe, Wedge
SUPPORT PILLOWS	Cervical Support, Wedge Pillow, Roll, Half-Roll, Abduction Pillow, Support Pillow
CERVICAL COLLARS	Soft Cervical Collar, Semi-Rigid Cervical Collar
ORTHOSES FOR SHOULDER AND CLAVICLE	Arm Sling, Arm Sling with Immobilizer, Clavicle Strap
POSITIONING ACCESSORIES	Abdominal Belt, Pelvis Belt, Immobilizer Vest, Pelvic Vest, Immobilization Glove
CHILDREN	Orthopedic Pillow COMFORT S, Arm Sling, Soft Cervical Collar, Semi-Rigid Cervical Collar
FOOT COMFORT	Pure Gel Digital Cap, Digital Cap, Pure Gel Ring, Digital Pad, Thick Toe Separator, Gel Separator, Small Bunion Gel Protector, Bunion Coated Protector, Pure Gel Metatarsal, Coated Metatarsal Cushion, Straight Toe Prop, Heel Pad Protector, Gel Tube, Gel Half Sock, Silicone Insole, Silicone Heel Cup, Heel Silicone 2 Densities, Heel 2 Densities, Heel Spur
CRUTCHES	SAFEWALK, COMFORT, ERGOTECH, ERGODYNAMIC

DATE

Anadia, June 2, 2014

SIGNATURE

INTERESPUMA – Ind. Poliuretanos, Lda.
A Gerência

José Afonso Melo
President

CE

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