Declaration of compliancy (E

Manufacturer: Spencer Italia Srl

Adress: Strada Cavi 7 -43044 Collecchio Parma - ITALIA

Product: PEDI FIX PAEDIATRIC HEADIMMOBILISER

Code: SH00260A

Classification (according to Council Directive 93/42/EEC, Annex IX): I

We hereby declare that the above mentioned products meet the provisions of 93/42/EEC Council Directive (MDD)

Application from the Annex VII (according to Council Directive 93/42/CEE)

Quality System Applied: ISO 9001-ISO 13485

Valid from date 07/09/2014

EDENCE TALIA S.I.I.

Signature an Position:_

Luigi Cesare Pizzi Spadoni

Legal Representative

The Declaration of conformity issued for the lot or production number is filed in the Device Master Record and is available from our company files.