

Declaration of Conformity

According to:

Council Directive 93/42/EEC (MDD)

Article 12

Legal Manufacturer's name: Shire Pharmaceuticals Limited

Manufacturing site name: DHL

Legal Manufacturer's address: 300 Shire Way Lexington, MA 02421 USA

Manufacturing site address: Bijsterhuizen 11-27, 6546AR Nijmegen, The Netherlands

We herewith declare that the following procedure packs meet the provisions of Article 12 of the above-mentioned Directive regarding:

- **The mutual compatibility of the medical devices included in the kit**
- **The relevant Manufacturer information supplied with the medical devices**
- **The packaging operations**
- **Control and inspection of the whole activity**

Product Name: Firazyr Pediatric Administration Kit

Product Family/Category: Procedure Pack

Classification: IIa

Classification Rule: MDD 93/42/EEC Article 12

GMDN Code Numbers: 47017: General Purpose Syringe

Name / Function: Ella Stamler / Head of Device Quality

Exton, PA USA

Signature: 

Place and Date of Issue:

12-16-2019

(MM-DD-YYYY)