Declaration of Conformity

According to: Council Directive 93/42/EEC

Annexes: Annex II (Excluding 4)

Notified Body Certificate(s): CE 679519

Notified Body's name and address: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands

Notified Body's identification number: 2797

Manufacturer's name and address: Shire Human Genetic Therapies, Inc., 300 Shire Way Lexington MA, 02421, USA

Authorized Representative's name and address: Shire Pharmaceuticals Ireland Limited, Shire block 3, Miesian Plaza 50-58, Lower Baggot Street, Dublin 2, D02 Y754, Ireland

+++We declare under our sole responsibility that the following product(s) conform to the applicable provisions of the above-mentioned Directive:+++

Product Name: FlowEase (Subcutaneous) Infusion Set

Product Family/Category: Subcutaneous Infusion Sets, Gamma Irradiation

Classification: IIa

Classification Rule: Rule 7

GMDN Code Numbers: 17180

+++This declaration is made on the following basis:

The validity of this document coincides with the date of the corresponding signature and remains effective until superseded by an updated DOC.
This document declares conformity for all product lots released after the date of issue.
Compliance to standards and regulations as defined in the Technical Documentation and Essential Requirements Checklist. +++

Name / Function: Chris Stevenson / Director DQA

Signature:

Place and Date of Issue: (MM-DD-YYYY) 16 Oct 2019

Declaration of Conformity

According to: Council Directive 93/42/EEC

Annexes: V

Notified Body Certificate(s): CE 679519

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+++We declare under our sole responsibility that the following product(s) conform to the applicable provisions of the above-mentioned Directive: +++

Product Name: Baxject II and Baxject II Hi-Flow

Product Family/Category: Reconstitution and Transfter Devices

Classification: Class I, Sterile

Classification Rule: Rule 2

GMDN Code Numbers: 16610

+++This declaration is made on the following basis:

The validity of this document coincides with the date of the corresponding signature and remains effective until superseded by an updated DOC.
This document declares conformity for all product lots released after the date of issue.
Compliance to standards and regulations as defined in the Technical Documentation and Essential Requirements Checklist. +++

Name / Function: Chris Stevenson / Director DQA

Signature: 

Place and Date of Issue: (MM-DD-YYYY) 16 Oct 2019