

Declaration of Conformity

According to: Regulation (EU) 2017/745

Manufacturer's Name/Registered Trade Name:

Takeda Pharmaceuticals U.S.A., Inc

SRN: US-MF-000014749

Address: 95 Hayden Ave, Lexington, Massachusetts 02421, USA

Authorized Representative's name: Shire Pharmaceuticals Ireland Limited

Address: Block 2 & 3 Miesian Plaza, 50 – 58 Baggot Street Lower,
Dublin 2, Ireland

SRN: IE-AR-000000593

Product Name: Natpar Pen

Product Code/Category:

5000418	Natpar Pen DE/AT
5000494	Natpar Pen NO/DK
5000495	Natpar Pen FI/SE
5000498	Natpar Pen UK
5000489	Natpar Pen NL
5000770	Natpar Pen GR/CY/IE
5000491	Natpar Pen ES

Intended Purpose: The Natpar Pen is a non-sterile, reusable pen intended for subcutaneous injection of Natpar medicine

Risk Classification: Class I

Basic UDI-DI Number: 0850025688Natpar_PenUH

***** We declare under our sole responsibility that the following product(s) conform to the applicable provisions of the above-mentioned regulation and relevant union legislation that provides for the issuing of an EU declaration of conformity*****

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The validity of this document coincides with the date of the corresponding signature and remains effective until superseded by an updated DOC.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 General Safety Performance Requirements (GSPRs).

Name / Function: Tara Cox, Head of Device Quality Compliance and Management Representative

Signature:

DocuSigned by:
Tara Cox


Place and Date of Issue: Dublin, Ireland

28-Jul-2022 | 14:44:17 BST

Signer Name: Tara Cox
Signing Reason: I approve this document
Signing Time: 28-Jul-2022 | 14:44:12 BST

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