# 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 Mixing Device

Product Code/Category:

| | |
|---|---|
| 5000416 | Natpar Mixing Device AT DE |
| 5000505 | Natpar Mixing Device DK NO |
| 5000771 | Natpar Mixing Device CY GR IE |
| 5000500 | Natpar Mixing Device UK |
| 5000501 | Natpar Mixing Device NL |
| 5000506 | Natpar Mixing Device FI SE |
| 5000503 | Natpar Mixing Device ES |

Intended Purpose: The Natpar Mixing Device is a reusable, non-active, non-sterile reconstitution device for reconstitution of a dual chamber cartridge (DCC) such as the PTH DCC used in Natpar for the treatment of hypoparathyroidism.

Risk Classification: Class I

Basic UDI-DI Number: 0850025688Natpar_MixingFX

***** 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The validity of this document coincides with the date of the corresponding signature and remains effective until superseded by an updated DOC.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

Signer Name: Tara Cox
Signing Reason: I approve this document
Signing Time: 28-Jul-2022 | 06:07:24 BST

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Place and Date of Issue: Dublin, Ireland

(MM-DD-YYYY) 28-Jul-2022 | 06:07:54 BST