TITLE	CUSTOMER COMPLAINT FORM

Date: _____ (dd/mmm/yyyy)

Use this form to report a device malfunction, use error, injury, or any adverse event associated with Medical Device. If the situation is medically urgent, please seek immediate medical attention before completing this form.

Section A- Reporter Information

A1. I am completing this form as a: ☐ Patient ☐ Caregiver ☐ Healthcare Professional (HCP)

☐ Other (specify): _____

A2. Age of the device user (years): _____ Age band: ☐ 12–17 (adolescent) ☐ 18–64 (adult) ☐ 65+ (older adult)

A3. Sex / gender: _____

A4. Country: _____

A5. Contact details (for follow-up, recommended):

A6. Email: _____

Section B- Device Information

B1. Medical Device serial number / lot number along with Manufacturing Details and Expiry Details (see device label): _____

B2. Approximate date of purchase / dispensing: _____

B3. Date when the problem occurred: _____

Section C- Description of The Complaint/ Event

C1. Type of issue (select all that apply):

☐ Device malfunction

☐ Suspected incorrect dose delivered

☐ Use error / difficulty operating the device

☐ Physical injury (e.g. skin reaction, needle-related injury)

☐ Adverse event / suspected side effect

☐ Labelling / Instructions for Use (IFU) issue

☐ Other (please describe below)

C2. Please describe what happened, in as much detail as possible/ if adverse event (share complete details):

_____

_____

_____

C3. Was medical attention sought? ☐ No ☐ Yes — please describe outcome:

_____

C4. Did the issue result in a missed or incorrect dose? ☐ No ☐ Yes — please describe:

_____

C5. Was a caregiver or HCP assisting at the time of the event? ☐ No ☐ Yes — role: _____

Section D- Consent and Submission

I understand this information will be used by the manufacturer for complaint-handling, vigilance and PMCF safety-monitoring purposes, in line with GDPR, and that the manufacturer may contact me for follow-up information.

How to Submit This Form?

- Online: Scan the QR code on your myPen2 packaging or Instructions for Use, or visit the manufacturer's website complaint page, and complete the same fields electronically. This is the fastest route and feeds directly into the vigilance system.
- Assisted: Contact the manufacturer's Pharmacovigilance Safety Toll-Free Helpline: 1800-258-8127 (Available 24 hours, 7 days a week, Free of charge) vigilance line and a representative will record your report on your behalf.
- This paper version may also be photographed/scanned and emailed to pv.safety@wockhardt.com, or given to your HCP or pharmacist to submit on your behalf.

Manufacturer internal use only

- Complaint ID: _____
- Date received: _____
- Received via (QR/mail/phone/paper): _____
- Triaged by: _____
- Reportable event? ☐ Yes ☐ No