DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue Silver Spring, MD 20993 (301)594-4695 Fax:(301)594-4715	10/20/2025-10/23/2025
	FEI NUMBER 3009871135

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Brian E Reece, Chief Executive Officer

FIRM NAME	STREET ADDRESS
Sheffield Precision Medical Limited	Unit 1, Wylcut House; 316 Petre Street; Shf
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Sheffield, SHF, S4 8LU United Kingdom	Medical Device Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Procedures for corrective and preventive action have not been adequately established.

Specifically,

A. You have not fully implemented your written procedure for Corrective & Preventive Action and Non-Conformance, SOP 003, Rev 20, Section 4.3 listing requirements for determining the underlying cause or "root cause" of the identified problem. Your records of Nonconforming Product which include a listed "root cause" investigation do not consistently demonstrate a complete investigation of to identify the underlying causes of the quality problem. For example,

(i) Records for Customer Non Conformance [redacted] received 06-OCT-2025, alleged that [redacted] Drill Guide Assembly devices, Part No. [redacted] Batch No. [redacted] did not meet the dimensional specification for one of the features of the Guide Bushing component. The record lists the feature of the Guide Bushing was likely out of specification due to the effects of tool wear, but the record does not demonstrate any further investigation to determine if you had adequate controls for monitoring tool wear, including

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but not limited to: written procedures for monitoring tool wear, records of monitoring tools and product for signs of tool wear, and operator training on monitoring for signs of tool wear. Further, you do not currently have such written procedures, records, or requirements for training.

(ii)Records for Customer Non Conformance No. [redacted] received 06-OCT-2025, alleged that a portion of the Drill Guide Assembly devices, Part No. [redacted], Batch No. [redacted] did not meet the dimensional specification for one of the features of the Guide Bushing component, and the records show you confirmed that [redacted] devices did not meet the specification. The record lists the feature of the Guide Bushing was likely out of specification due to the effects of tool wear, but the record does not demonstrate any further investigation to determine if you had adequate controls for monitoring tool wear, including but not limited to: written procedures for monitoring tool wear, records of monitoring tools and product for signs of tool wear, and operator training on monitoring for signs of tool wear. Further, you do not currently have such written procedures, records, or requirements for training.

B.You have not fully implemented your written Corrective & Preventive Action and Non-Conforming Product procedure, SOP 003, Issue 17, requiring under Section 4.3 the investigation of a nonconforming product to determine possible "root cause" of the identified problem and to propose corrective actions. Your records of Nonconforming Product which include a listed "root cause" investigation do not consistently demonstrate a complete investigation of to identify the underlying causes of the quality problem. For example, records for Customer Non Conformance No. [redacted] received 23-AUG-2024, alleged that [redacted] Distal Fixation Ring Trial devices, Part No. [redacted] did not meet dimensional specifications for the outer diameter. The record lists you found the cause was related to rework, but the record does not list the

investigation which led you to determine this was the underlying cause, and you do not have any records showing there was ever any rework of the subject devices, Batch No. (b)(4), to support this as the likely underlying cause. Further, you have no records demonstrating your investigation into the accuracy of the instrument used to perform verification of the diameter specification or records showing your review of the device history record to investigate any discrepancies or abnormalities which might have caused the devices to be out of specification. In addition, I conducted a review of the production records for Batch No. (b)(4), and I found the records indicate there was or may have been an additional (b)(4)

OBSERVATION 2

Schedules for the adjustment, cleaning, and other maintenance of equipment have not been established.

Specifically, you do not have written procedures defining requirements for periodic monitoring of the automated turning process used to manufacture medical devices at your factory, to evaluate tool wear and identify when an adjustment is required for the offset of the tools used for the turning process and/or when there is a need to replace the tools.

Further, you do not have records demonstrating the inspection of tools and of the work product which you routinely perform to identify the need to adjust the offset of tools or change the tools when required to ensure devices meet finished product specifications.

OBSERVATION 3

Inherent limitations or allowable tolerances are not posted on or near and are not readily available to personnel performing adjustments of equipment requiring periodic adjustments.

Specifically, there are no limitations for adjustment of the automated turing machines used to produce medical devices at your factory, including but not limited to production of the orthopedic implant screw

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devices, P/N (b)(4) although you routinely make adjustments to the equipment settings. For example,

A. The set-up process for the turning machine, which is carried out at the start of a production batch, includes making adjustments to the offset values for each tool in order to ensure finished devices meet specifications, but the limit to the amount of adjustment to the offset values which are permitted is not posted on the turning machine or otherwise readily accessible to the persons setting-up the turning machine.

B. The operators of the automated turning machines periodically make adjustments to the offset values for the tools of the equipment, to account for tool wear, but neither the limits for adjustment of the offset values nor a limit of the frequency with which to make such adjustments is listed on the turning machines or are otherwise readily accessible to the persons operating the equipment and making these adjustments to the offset values.

OBSERVATION 4

Procedures for the acceptance and control of in-process product have not been established.

Specifically,

A. Your production workers operating the automated turning machines used to manufacture medical devices, including an orthopedic implant screw device, Part No. (b)(4) periodically verify the devices produced by the equipment meet specifications, which is information utilized as a process monitoring activity to identify the effects of tool wear and, thus, indicate if there is a need to adjust the offset values for the tools or to change the tools. You do not have written procedures defining the frequency with which such product inspection activities are to be carried out in order to ensure the effects of tool wear do not result in production of devices which do not meet specifications.

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B. Your production and inspection records do not consistently list the dates all in-process inspections were performed, the results of those inspections, the signature of the person conducting those inspections, and the equipment or instruments used to perform those inspections. For example,

i. Production and inspection records under covering for the turning process used to produce the Guide Bushing component, manufactured [redacted] under Work Order No. [redacted] do not list any inspections of the components other than the first article and the last article produced. Your Technical Director confirmed that, based in part on a production volume of [redacted] the production personnel would have performed at least some periodic inspections of devices during the manufacturing process. These Guide Busing components were utilized in the production of Drill Guide Assembly devices, Part No. [redacted], under Work Order No. [redacted]

ii. Production and inspection records under covering for the turning process used to produce the Guide Bushing component, manufactured [redacted] under Work Order No [redacted] do not list any inspections of the components other than the first article and the last article produced. Your Technical Director confirmed that, based in part on a production volume of [redacted] the production personnel would have performed at least some periodic inspections of devices during the manufacturing process. A portion of these Guide Busing components were utilized in the production of Drill Guide Assembly devices, Part No. [redacted] under Work Order No. [redacted]

Further, the inspection records for the Guide Bushing components, manufactured under under Work Order No. [redacted] list neither the asset number nor the type of equipment/instrument used to perform the in-process verifications, including those used for the verification of the first article and last article produced.

OBSERVATION 5

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A process whose results cannot be fully verified by subsequent inspection and test has not been adequately validated according to established procedures.

Specifically, you have not fully validated (b)(4) used to manufacture medical devices, including but not limited to the Drill Guide device, Part No. (b)(4) the Broach Handle Assembly device, Part No. (b)(4) and the orthopedic implant screw device, Part No. (b)(4) For example,

A. Your Operational Qualification Protocol, OQ-P 017, dated 8-MAR-2018, and the associated Operational Qualification Report, OQ 017, dated 16-MAR-2018, do not fully demonstrate characterization of (b)(4) used to process the devices you manufacturer in order to determine the capability of the process to achieve specified requirements over the operating range for the identified critical parameters. For example,

(i) The protocol does not define and the report does not demonstrate any testing to evaluate results of possible (b)(4)

(b)(4)

(ii) The protocol does not define and the report does not demonstrate that the test coupons evaluated under this effort demonstrate at least an equivalent challenge to the achieving specified requirements through (b)(4) as compared to those medical devices you manufacture utilizing this process.

(iii) The report records do not include records of the critical process parameters under which these qualification batches were run, in order to demonstrate that the batches were run under the parameter settings or ranges listed in the protocol, and you do not otherwise have records listing

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the process parameters for these qualification batches.

(iv) The Engineering Study, ES 017, report dated 16-MAR-2016, does not adequately demonstrate the capability of the (b)(4) This Engineering Study did not:

(b)(4)

B. Your Performance Qualification Protocol, PQ-P 017, dated 16-MAR-2018, and the associated Performance Qualification Report, PQ 017, dated 19-MAR-2018, do not fully demonstrate the (b)(4) for the medical devices you manufacture, consistently and with a high level of assurance. For example,

The report does not demonstrate testing results under this effort are clearly indicative of the (b)(4) prior the qualification protocol and the time when this testing was performed, with the devices evaluated under this effort processed

as long ago as June of 2010 but the testing performed sometime after the protocol was approved in March of 2018.

(ii) The protocol does not define and the report does not include any evaluation of the medical devices manufactured at your factory as compared to those medical devices evaluated under this effort, in order to show the devices evaluated demonstrate at least an equivalent challenge to the (b)(4) as is presented by the entire family of medical devices under the scope of this qualification effort.

Further, the records of the devices evaluated under this effort show that not all of these devices were (b)(4) (b)(4)

Additionally, you do not have records demonstrating your evaluation to consider that additional devices which you have begun to manufacture at your factory since this qualification effort was carried out do not present a greater challenge to (b)(4) and, thus, that the process specifications covered under this effort may be valid for processing these additional devices. The additional devices which you began manufacturing after completion of this qualification effort include but are not limited to the Drill Guide device, Part No. (b)(4) the Broach Handle Assembly device, Part No. (b)(4) and the orthopedic implant screw device, Part No. (b)(4)

(iii) The protocol does not define and the report does not demonstrate any testing to evaluate results of possible (b)(4) and does not otherwise demonstrate there are no adverse results from

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(b)(4)

(b)(4)

C. Your Performance Qualification Protocol, Validation Addendum Protocol 2, dated 14-SEP-2020, and the associated Performance Qualification Report, dated 20-SEP-2020, do not fully demonstrate (b)(4)

(b)(4)

For example, the protocol does not define and the report does not demonstrate any testing to evaluate results of possible (b)(4) and does not otherwise demonstrate there are no adverse results from (b)(4)

(b)(4)

D. You do not have records covering an effort to validate the (b)(4) process, defined under (b)(4) which is utilized to manufacture the Drill Guide devices and the Broach Handle Assembly devices you manufacture.

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E. You do not have records covering an effort to validate [(b)(4)] used for components of the Drill Guide devices manufactured from [(b)(4)]

OBSERVATION 6

The device history record does not demonstrate that the device was manufactured in accordance with the device master record and 21 CFR 820.

Specifically,

A. Your device history records covering the [(b)(4)] orthopedic screw implant device, Part No. [(b)(4)], do not include or reference the information for the dates of manufacture. On 20-OCT-2025, I visited your production floor and observed the records covering the turning process used to produce this orthopedic implant screw device, under Work Order No. [(b)(4)] did not list the date for the set-up of the turning machine and production of the first device, although the record listed the first device manufactured under this Work Order had been verified by the inspection team.

B. Your device history records covering the Drill Guide device, Part No. [(b)(4)] do not demonstrate you consistently manufactured the device according to your defined production process. For example, the records for Work Order Nos. [(b)(4)] list the [(b)(4)] was carried out with [(b)(4)] [(b)(4)]

C. Your device history records covering Drill Guide device, Part No. [(b)(4)] manufactured under Work Order No. [(b)(4)] do not include a record listing the approved disposition for products requested to be reworked, nor do these records include or reference the

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rework and retesting activities carried out on those devices which were identified as not conforming to specified requirements.

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Annotations to Observations

Observation 1: Not annotated

Observation 2: Not annotated

Observation 3: Not annotated

Observation 4: Not annotated

Observation 5: Not annotated

Observation 6: Not annotated

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."