



Medicines & Healthcare products
Regulatory Agency

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[MHRA Website](https://www.mhra.gov.uk)

Our Ref: **FOI2026/00926**

16 September 2026

Dear [REDACTED]

Thank you for your Freedom of Information (FOI) request received on 19 August 2026. You wrote:

We act on behalf of a client in relation to a potential claim for damages with respect to Cartiva Synthetic Cartilage Toe Implants ("the relevant product"), which were inserted into both of our client's feet, as treatment for osteoarthritis. Our client has since required revision surgery.

We understand that NICE withdrew guidance (published in 2022) on the relevant product following a recall notice issued by the manufacturer Stryker on 31 October 2024. Please see attached recall notice

MHRA reference: 33744394 2024/010/028/601/045

As part of our investigations into a potential damages claim we would be grateful if you would provide such relevant information/documents concerning the Regulation/Registration of the relevant product insofar as it's placing on the UK market is concerned, to include;

- 1. The Statutory Instrument under which the relevant product was first permitted to be placed on the UK Market (and details of any subsequent/amending Statutory Instruments)*
- 2. The date upon which the relevant product was first registered/notified in the UK and any documents concerning its registration*
- 3. Confirmation of the device classification of the relevant product under the relevant legislation*
- 4. Confirmation of the conformity assessment procedure applicable to the relevant product*
- 5. Details of the relevant Notified Body/UK Approved Body who undertook the original conformity assessment procedure on the relevant product and any subsequent change of Body*
- 6. A copy of any Declaration of Conformity (EC/EU or UK)*
- 7. A copy of any EC/EU Type Examination Certificate and Certificate Number (and any renewal/extension of certificates or amended Certificates)*
- 8. Copies of any Technical Documentation relating to the relevant product*
- 9. Confirmation as to whether there had been any change to the relevant product's Regulatory status since being first placed on the UK market*

10. Documents concerning the recall notice/removal of the relevant product from the UK market

Please treat this email as a Freedom of Information request.

MHRA Response

Please see below our response to each of your questions below.

1. *The Statutory Instrument under which the relevant product was first permitted to be placed on the UK Market (and details of any subsequent/amending Statutory Instruments)*
Information on the regulation of medical devices is already in the public domain through the MHRA's *Guidance on the registration requirements for medical devices placed on the market at put into service*, EC Directive 93/42/EEC and *The Medical Devices Regulations 2002*. Links to these are provided below:

https://assets.publishing.service.gov.uk/media/6a5dd9497eb057103bd946bb/Placing_on_the_market_putting_into_service_guidance.pdf

[Council Directive 93/42/EEC of 14 June 1993 concerning medical devices](#)

<https://www.legislation.gov.uk/ukxi/2002/618/contents/made>

2. *The date upon which the relevant product was first registered/notified in the UK and any documents concerning its registration*
Cartiva Synthetic Cartilage Toe Implants (catalogue reference CAR-06, CAR-08, CAR-10, CAR-12 and CMC-08) were first registered with MHRA on 10 January 2024.

3. *Confirmation of the device classification of the relevant product under the relevant legislation*
These products were registered as Class IIb medical devices GMDN33696 (partial metatarsophalangeal joint prosthesis) and GMDN 40126 (metacarpal prosthesis), in line with the EC Certificate of quality assurance, which classified these as "sterile, non-absorbable, implantable, biomaterial devices for cartilage replacement and the associated sterile disposable instruments."

4. *Confirmation of the conformity assessment procedure applicable to the relevant product*
Please see Annex II (excluding Section 4) of EC Directive 93/42/EEC, linked below.

[Council Directive 93/42/EEC of 14 June 1993 concerning medical devices](#)

5. *Details of the relevant Notified Body/UK Approved Body who undertook the original conformity assessment procedure on the relevant product and any subsequent change of Body*

An EC Certificate of quality assurance was issued by the British Standards Institute (BSI).

6. *A copy of any Declaration of Conformity (EC/EU or UK)*
MHRA does not hold a copy of the Declaration of Conformity for these registrations.

7. *A copy of any EC/EU Type Examination Certificate and Certificate Number (and any renewal/extension of certificates or amended Certificates)*

8. *Copies of any Technical Documentation relating to the relevant product*

We hold a copy of the EC Certificate of quality assurance which was issued by the British Standards Institution (BSI), in line with the requirements for device registration. This certificate is exempt under Section 41 (information provided in confidence), Section 43 (commercial interests) and Section 44 (prohibition on disclosure). We will provide more detail on these exemptions below.

Section 41:

(1) Information is exempt information if — (a) it was obtained by the public authority from any other person (including another public authority), and, (b) the disclosure of the information to the public (otherwise than under this Act) by the public authority holding it would constitute a breach of confidence actionable by that or any other person.

Section 43:

(1) Information is exempt information if it constitutes a trade secret.

(2) Information is exempt information if its disclosure under this Act would, or would be likely to, prejudice the commercial interests of any person (including the public authority holding it).

Regarding the use of Section 41, the information you have requested relates to the manufacturing sites for a medical device that has been registered with MHRA. This information was obtained from the company registering the device and the Agency believes that if this information were released it would be an actionable breach of confidence. Therefore, we are not going to be releasing the requested information.

Regarding the use of Section 43, this exempts information which if disclosed would be likely to prejudice the commercial interests of any person including a public authority. It protects not only the commercial interests of third parties, but also the commercial interests of the Agency. It is intended to protect the ability of a public authority like MHRA to obtain goods or services on the best possible commercial terms and to protect the legitimate commercial interests of its suppliers. The information you seek falls into this category. In order to apply Section 43 properly, a consideration of the public interest (public interest test) is required.

Public interest test

Section 17(3) of the Act requires us to conduct a Public Interest Test (PIT) when applying of a qualified exemption. In applying this exemption, we are required to consider whether, in all the circumstances of the case, the public interest in withholding the information outweighs the public interest in releasing the information held. The 'public interest' is not the same as what interests the public. In carrying out a PIT, we consider the greater good or benefit to the community as a whole in withholding. The 'right to know' must be balanced against the need to enable effective procedural governance and to serve the best interests of the public. The FOI Act is 'applicant blind'. This means that we cannot, and do not, ask about the motives of anyone who asks for information. In providing a response to one person, we are expressing a willingness to provide the same response to anyone.

Considerations in favour of releasing the information

To release this information would benefit in general by showing transparency in MHRA's day-to-day work to the public for the public to see the EC Certificate of quality assurance in full.

Considerations in favour withholding the information

Information on the sites used for the manufacture of a medical device is commercially sensitive information that has been provided to MHRA in confidence. To publish this information would be to provide competitor companies with information on where the medicinal device is manufactured, which would help them overcome hurdles in the development of their own medicinal products, at the expense of this device manufacturer.

On balance we are satisfied that, in this instance, the public interest in applying the exemption outweighs the public interest in disclosure.

Section 44(1) – Prohibition on disclosure

Section 44 of the FOI Act concerns prohibitions on disclosure. The information you have requested relates to Prohibitions on Disclosure and under Section 44(1)(a) of the FOI Act we are exempt from providing this information if it is prohibited due to other legislation. In this case, Section 237 of the Enterprise Act 2002 prohibits a public authority from releasing information which came to it in connection with the exercise of its functions, and which relates to the affairs of an individual or business.

The MHRA is satisfied that the information you have requested:

- constitutes information which came to us in connection with the exercise of the Agency's functions. The MHRA has a duty of consumer protection under the Consumer Protection Act 1987 which is listed as a specified function under Schedule 14 of the Enterprise Act 2002 and receives information while exercising consumer protection functions in its role as the regulator of medicines and healthcare products.
- relates to the affairs of businesses involved in this device registration.

On that basis we are satisfied that Section 44 of FOI Act applies, and the information is exempt from release. Further information on MHRA's Advertising Department's role in consumer protection is available in Part 14 of The Human Medicines Regulations 2012 and the Consumer Protection Act 1987, both of which are linked below.

<https://www.legislation.gov.uk/ukxi/2012/1916/part/14>

<https://www.legislation.gov.uk/ukpga/1987/43/contents>

9. Confirmation as to whether there had been any change to the relevant product's Regulatory status since being first placed on the UK market

These products were unregistered from the Devices Register on 30 May 2024. The reason given for taking these from the register was that *"the manufacturing organisation has ceased trading."*

We're not aware of any legal notices that have been served by Compliance which would have affected regulatory status.

10. Documents concerning the recall notice/removal of the relevant product from the UK market

MHRA holds no information relevant to this and are not aware of any legal notices served by Compliance which resulted in the removal of the product from the market. Please note that MHRA does not grant clearance or approval for medical devices, outside of exceptional circumstances.

Registration of medical devices with the MHRA (the UK Competent Authority) does not represent any form of clearance, accreditation, certification, approval, or endorsement by the MHRA. The manufacturer holds the legal responsibility for obtaining the necessary certification and registering their medical devices with MHRA. Higher risk medical devices are assessed and approved by Approved Bodies in the UK or Notified Bodies in the EU.

If you have any queries about this letter, please contact us quoting the reference number above.

Yours sincerely,

MHRA Central Freedom of Information Team
Medicines & Healthcare products Regulatory Agency

Your right to complain under the Freedom of Information Act

If you are not happy with this response you may request an internal review by e-mailing foi.request@mhra.gov.uk or by writing to: MHRA Central Freedom of Information Team, 10 South, Colonnade, Canary Wharf, London, E14 4PU

Any request for an internal review must be received by us within 40 working days of the date of this letter. Please note we are not obliged to provide a review if it is requested after more than 40 working days.

If you are not content with the outcome of the internal review you may apply directly to the Information Commissioner's Office for a decision. Generally, the Commissioner cannot make a decision unless you have exhausted our own complaints procedure. The Information Commissioner can be contacted at: The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF.

Website: [ICO FOI and EIR complaints](#) or telephone 0303 123 1113.

Re-use of our information

The MHRA information supplied in response to your request is subject to Crown copyright. Information created by the MHRA which is disclosed under the Freedom of Information Act is made available for re-use under the Open Government Licence (OGL) v3.0, except where this is otherwise stated. There are some restrictions on re-use under the OGL and these can be viewed here:

<https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/>