Device/manufacturer registration - Reference: 202303140129871 8

SUMMARY | DEVICES | NEWS

Devices

44757 - Synovial fluid supplementation medium

Device information

Definition

A sterile viscous/elastic solution or gel (e.g., comprised of hyaluronic acids and their polymeric derivatives) intended to be injected into joints (particularly large, load-bearing joints such as the hip or knee) to help cushion the joint, especially in cases of endogenous synovial fluid reduced viscosity from degenerative disease.

Device type

General Medical Device

Which directive/regulation does this device comply with?

Directive 93/42/EEC

Custom made?

No

Risk classification

Class III

Sterile?

Yes

Method of Sterilisation

Steam

Single use device?

Yes

Reprocessed single-use device?

No

Are any of the products related to this device implantable?

Yes

Are any of the products related to this device active?

Yes

Device intended to administer and/or remove medicinal product?

Yes

Basic UDI-DI Issuing Entity

GS1 AISBL

Basic UDI-DI Number

00866142CINGAB6

Presence of a substance which, if used separately, may be considered to be a medicinal/herbal medicinal product

No

Presence of a substance which, if used separately, may be considered to be a medicinal product derived from human blood or human plasma

No

Conformity Assessment Certificates

You must provide UKCA/CE/CE(UK NI) certificates from a UK Approved Body/Notified Body for the device: 44757-Synovial fluid supplementation medium

For this device you need to provide **one** of the following UKCA/CE/CE(UK NI) certificate options:

- **Medical Devices Directive 93/42 EEC**
  - Option 1: Full Quality Assurance (Annex II excluding Section 4) and Design Examination Certificate (Annex II with Section 4)
  - Option 2: Type Examination (Annex III) and Batch Verification (Annex IV)
  - Option 3: Type Examination (Annex III) and Production Quality Assurance (Annex V)

- Option 4: Type Examination (Annex III), Batch Verification (Annex IV) and Production Quality Assurance (Annex V)

- **Medical Devices Regulation (EU) 2017/745**
  - Option 5: Quality Management System (Annex IX, Chapters I, III) and Assessment of Technical Documentation (Annex IX, Chapter II)
  - Option 6: Type Examination (Annex X) and Production Quality Assurance (Annex XI, Part A)
  - Option 7: Type Examination (Annex X) and Production Verification (Annex XI, Part B)

Find out more about UKCA, CE certificates, UK Approved Bodies and EU Notified Bodies. See also the EU directive 93/42/EEC and the Medical Devices Regulation (EU) 2017/745.

Filename	Reference	Expiry date		Certificate type	UK Approved Body/EU Notified Body	Conformity Assessment Type
FQAS GMED Cert No 36826 Rev 1 expires_ 2024_0412	36826 rev 1	12/04/2024		Full Quality Assurance (Annex II excluding Section 4)	GMED SAS	CE - MDD/IVDD/AIMD
GMED_36680 rev 3_ ISO 13485_expires 2025_0412	36680 rev 3	12/04/2025		Production Quality Assurance (Annex V)	GMED SAS	CE - MDD/IVDD/AIMD
GMED_36681 rev 1_MDSAP_expires 2025_0328	36681 rev 1	28/03/2025		Production Quality Assurance (Annex V)	GMED SAS	CE - MDD/IVDD/AIMD
DC_37213.3_ Cingal	37213 rev 3	26/05/2024		Design Examination Certificate (Annex II with Section 4)	GMED SAS	CE - MDD/IVDD/AIMD
Cingal MDD EC Cert Rev 2 -accompany Doc 37213	36822 rev 2	26/05/2024		Design Examination Certificate (Annex II with Section 4)	GMED SAS	CE - MDD/IVDD/AIMD

5 items

Products (4)

Preview only displays limited fields

Medical Device Name (Brand/Trade/Proprietary or Common name)	Model/Version	Catalogue/Reference (REF)	UDI Issuing Entity	UDI Device Identifier (UDI-DI)	Product Status
Cingal	No	695003	GS1 AISBL	00866142000076	On the GB & NI market
Cingal	No	695004	GS1 AISBL	00817337000159	On the GB & NI market
Cingal	No	695007	GS1 AISBL	00817337000166	On the GB & NI market
Cingal	No	695008	GS1 AISBL	00817337000173	On the GB & NI market

Device **registered** on 15 March 2023 09:43 by MHRA Staff.

BACK