Manufacturer Evidence

Status : Approved

Certificate change history

Version 1 - EC Certificate accepted (s22 [redacted], 8/03/2011)
Version 2 - Accepted. Updated EC Certificate added. The sponsor has indicated in the manufacturers evidence application that 'the scope of the certificate has changed' and the 'scope of the certificate still covers all the ARTG entries linked to this evidence' (s22 [redacted] 20/06/2017)
Version 3 - Accepted Updated EC Cert added The sponsor has indicated in the manufacturers evidence application that 'the scope of the certificate has changed' and the 'scope of the certificate still covers all the ARTG entries linked to this evidence'. s22 [redacted], 19/10/2020)

Date received:	09/10/2020
Certificate printed:	No

Variation to Evidence ID: DV-2011-MC-02920-3

Notification details

Evidence identifier:	DV-2011-MC-02920-3
Submission identifier:	DM-2020-08164-1
Version number:	3
Sponsor's own reference:	FH; ESP

Sponsor details

Agent name:	
Sponsor name:	Orthotech Pty Ltd
Contact details:	s22 [redacted]

Certification details

Manufacturer name:	FH Industrie (France)[40855]
Manufacturer address as on certification:	6 Rue Nobel Z.I. de Kernevez QUIMPER 29000 France S [144434]

Type of product:
This certification is to support an application for a medical device that is not an in vitro diagnostic medical device (IVD)

Certificate issued under:	02
Conformity assessment procedure:	Schedule 3 Part 1 (Annex II)
Source of certification:	Laboratoire national de metrologie et d'essais / G-MED [0459]
Certificate number:	8861 rev 26
Certificate issue date:	20/08/2010
Certificate expiry date:	26/05/2024
Certificate re-issue date:	10/09/2020
Restrictions on scope:	

Restriction on conformity assessment procedure:
Full Quality Assurance Certificate.

Attached documentation:

Attached documents: EC Certificate - Certificat_8861-26_IIA-IIB-III.pdf

Supporting documents:			
#	Document Type	Description	Method

Related Active ARTG Entry Information:

History

CN=s22 OU=TGA/O=Health