



Signature Orthopaedics Pty Ltd
7 Sirius Road
Lane Cove West, NSW 2066
Australia

16th July 2024

RE: Change in branding of femoral stem device from Aria to Everglade – Signature Orthopaedics

To Whom It May Concern,

This letter is to confirm that Everglade stem device manufactured by Signature Orthopaedics is the same as device previously manufactured under name 'Aria' and includes all part numbers/catalogue numbers that were previously under name 'Aria'. The device name 'Aria' underwent a branding change to 'Everglade' in order to consolidate the device branding in various market regions from 'Aria' to 'Everglade'. Corresponding part numbers that underwent branding change are provided in Appendix A.

We confirm that the part numbers listed in Appendix A are in scope of Signature Orthopaedics' contract with BSI for EU MDR. The Everglade stem (previously Aria) holds USA FDA clearance, and Australia TGA approval under name Everglade – see attached TGA CA certificate.

Signature Orthopaedics Pty Ltd is the same legal entity with the same Quality Management System as Signature Orthopaedics Europe Ltd, and the difference in business names is due to geographical location and administrative purposes only. Both Signature Orthopaedics Pty Ltd and Signature Orthopaedics Europe Ltd are the same manufacturer of Everglade (previously Aria) femoral stem device.

Yours truly,

A handwritten signature in black ink, appearing to read "Declan Brazil", is written over a light blue horizontal line.

Declan Brazil,
CEO
declan@signatureortho.com.au

Appendix A – List of Relevant ARTGs

Part number	Description
111-20-6000	Everglade Stem, Standard Offset size 0
111-20-6001	Everglade Stem, Standard Offset size 1
111-20-6002	Everglade Stem, Standard Offset size 2
111-20-6003	Everglade Stem, Standard Offset size 3
111-20-6004	Everglade Stem, Standard Offset size 4
111-20-6005	Everglade Stem, Standard Offset size 5
111-20-6006	Everglade Stem, Standard Offset size 6
111-20-6007	Everglade Stem, Standard Offset size 7
111-20-6008	Everglade Stem, Standard Offset size 8
111-20-6009	Everglade Stem, Standard Offset size 9
111-20-6010	Everglade Stem, Standard Offset size 10
111-20-6011	Everglade Stem, Standard Offset size 11
111-20-6012	Everglade Stem, Standard Offset size 12
111-20-6100	Everglade stem, High Offset size 0
111-20-6101	Everglade stem, High Offset size 1
111-20-6102	Everglade stem, High Offset size 2
111-20-6103	Everglade stem, High Offset size 3
111-20-6104	Everglade stem, High Offset size 4
111-20-6105	Everglade stem, High Offset size 5
111-20-6106	Everglade stem, High Offset size 6
111-20-6107	Everglade stem, High Offset size 7
111-20-6108	Everglade stem, High Offset size 8
111-20-6109	Everglade stem, High Offset size 9
111-20-6110	Everglade stem, High Offset size 10
111-20-6111	Everglade stem, High Offset size 11
111-20-6112	Everglade stem, High Offset size 12