





Certificate

No. Q8 094719 0005 Rev. 00

Holder of Certificate: Gwalia Healthcare Ltd

Unit B4

Taffs Mead Road

Treforest Industrial Estate

Pontypridd, Mid Glamorgan CF37 5TF

UNITED KINGDOM

Gwalia Healthcare Ltd Facility(ies):

Unit B4, Taffs Mead Road, Treforest Industrial Estate, Pontypridd,

Mid Glamorgan CF37 5TF, UNITED KINGDOM

See Scope of Certificate

Certification Mark:



The Provision of the manufacture of injection **Scope of Certificate:**

moulded components, sub-assemblies and finished products for general non-active nonimplantable and active non-implantable medical

devices.

EN ISO 13485:2016 **Applied Standard(s):**

Medical devices - Quality management systems -

Requirements for regulatory purposes

(ISO 13485:2016) DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q8 094719 0005 Rev. 00

Report No.: 75954127

2022-06-10 Valid from: 2025-03-31 Valid until:

Date. 2022-06-10

Christoph Dicks

Head of Certification/Notified Body