15 October 2024 8 October 2027 10641346

Original approval(s): ISO 13485 - 2 August 2016

LRQA

Certificate of Approval

This is to certify that the Management System of:

Sioux Technologies B.V.

Esp 130, 5633 AA Eindhoven, The Netherlands

has been approved by LRQA to the following standards:

ISO 13485:2016

Approval number(s): ISO 13485 - 0025437

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

The scope of this approval is applicable to:

Design and development of high tech software, mathware, electronic and mechatronic components and systems ranging from concept design to prototyping and production of one-offs for medical device customers.

Regional Director, Europe

Marta Escudero

Issued by: LRQA Limited





Certificate identity number: 10641346

Certificate Schedule

Location **Activities**

Sioux Technologies B.V.

Esp 130, 5633 AA Eindhoven, The Netherlands

ISO 13485:2016

Design and development of high tech software, mathware, electronic and mechatronic components and systems ranging from concept design to prototyping and production of one-offs for medical device customers.

Sioux Technologies B.V.

Rotterdamseweg 183C, 2629 HD Delft, The Netherlands

ISO 13485:2016

Design and development of high tech software, mathware, electronic and mechatronic components and systems ranging from concept design to prototyping and production of one-offs for medical device customers.

Sioux Technologies B.V.

Communicatieweg 5, 3641 SG Mijdrecht, The Netherlands

ISO 13485:2016

Design and development of high tech software, mathware, electronic and mechatronic components and systems ranging from concept design to prototyping and production of one-offs for medical device customers.

LRQA Group Limited, its affiliates and subsidiaries and their respective officers, employees or agents are, individually and collectively, referred to in this clause as 'LRQA'. LRQA assumes no responsibility and shall not be liable to any person for any loss, damage or expense caused by reliance on the information or advice in this document or howsoever provided, unless that person has signed a contract with the relevant LRQA entity for the provision of this information or advice and in that case any responsibility or liability is exclusively on the terms and conditions set out in that contract. Issued by: LRQA Limited, 1 Trinity Park, Bickenhill Lane, Birmingham B37 7ES, United Kingdom

Page 2 of 2

LRQA

LRQA