By Royal Charter

# EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

**No.** **CE 77819**

Issued To: **Ad-Tech Medical Instrument Corporation**
**400 West Oakview Parkway**
**Oak Creek**
**Wisconsin**
**53154**
**USA**

In respect of:

**Subdural Electrodes**

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2003-12-12** Date: **2020-03-04** Expiry Date: **2024-05-26**

...making excellence a habit.™

# EC Design-Examination Certificate

**Supplementary Information to CE 77819**

Issued To:

**Ad-Tech Medical**
**Instrument Corporation**
**400 West Oakview Parkway**
**Oak Creek**
**Wisconsin**
**53154**
**USA**

Product Specific certificate:

| Catalogue Number | Device Name | Model, Type | Intended purpose per IFU | Classification |
|---|---|---|---|---|
| $X_{1-2}\,X_{3-4}\,X_5$ - $Y_1\,Y_2\,Y_{3-4}\,Y_5$ - $Z_1\,Z_{2-3}$<br>* See below | Subdural Electrodes | Strip Electrodes<br>$X_{1-2}\,X_{3-4}\,X_5$ - $Y_1\,Y_2\,Y_{3-4}\,Y_5$ - $Z_1\,Z_{2-3}$ | The Ad-Tech Subdural Electrodes are intended for temporary (<30 days) use with recording, monitoring, and stimulation equipment, for the recording, monitoring and stimulation of electrical signals at the subsurface level of the brain. The recording of electrical activity supports definition of the location of epileptogenic foci and brain mapping. | Class III |
| $X_{1-2}\,X_{3-5}$ - $Y_1\,Y_2\,Y_{3-4}\,Y_5$ - $Z_1\,Z_{2-3}$<br>**See below | | Grid and Dual-Sided Electrode<br>$X_{1-2}\,X_{3-5}$ - $Y_1\,Y_2\,Y_{3-4}\,Y_5$ - $Z_1\,Z_{2-3}$ | | Class III |

First Issued: **2003-12-12** Date: **2020-03-04** Expiry Date: **2024-05-26**

...making excellence a habit.™

# EC Design-Examination Certificate

**Supplementary Information to CE 77819**

Issued To:

**Ad-Tech Medical**
**Instrument Corporation**
**400 West Oakview Parkway**
**Oak Creek**
**Wisconsin**
**53154**
**USA**

## *Strip Electrodes

$$X_{1-2}\ X_{3-4}\ X_5\ -\ Y_1\ Y_2\ Y_{3-4}\ Y_5\ -\ Z_1\ Z_{2-3}$$

Where:

$X_{1-2}$ = The design intent code.

Values =FS, IS, MS, NS, PS, RS, TS, or ZS

$X_{3-4}$ = The number of contacts. Range from 1 - 16.

$X_5$ = The tail color code. Values range from A - Z.

$Y_1$ = The contact shape code. Values are alphabetical A-N and S

$Y_2$ = The contact material code. 2 Values, P for platinum; S for stainless steel.

$Y_{3-4}$ = The contact spacing code. Values range from 00 - 99. At the present time, codes 00-20

indicate the spacing, in mm, from the center of one contact to the center of the other. For values from 0-20mm all spacings are uniform. For numbers above 20 the spacings are variable.

$Y_5$ = The sterility status code. X for sterile

$Z_1$ = The body shape code. Values range from A - Z & 0-9.

$Z_{2-3}$ = Additional non-significant options. Values range from 00-99, A0-Z9 & AA-ZZ.

- Electrode body options, such as curvature,
- Tail options include where it comes out of the body of the electrode, the angle of exit, whether it exits at the top or bottom, length of the tail (shorter or longer)
- Marker options

First Issued: **2003-12-12** Date: **2020-03-04** Expiry Date: **2024-05-26**

# EC Design-Examination Certificate

**Supplementary Information to CE 77819**

Issued To:

**Ad-Tech Medical**
**Instrument Corporation**
**400 West Oakview Parkway**
**Oak Creek**
**Wisconsin**
**53154**
**USA**

**<u>Grid and Dual-Sided Electrode</u>**

**$X_{1-2}$ $X_{3-5}$ - $Y_1$ $Y_2$ $Y_{3-4}$ $Y_5$ - $Z_1$ $Z_{2-3}$**

Where

$X_{1-2}$ = The design intent code.

Grid electrodes - AG, BG, FG, GG, HG, IG, MG, RG, TG, VG or WG

Dual Sided - DG, DH, DR or DS

$X_{3-5}$ = The contact array & tail configuration code. Range = 3-128 (coded as 03A-Z8Z)

$Y_1$ = The contact shape code. Values are alphabetical A-N and S

$Y_2$ = The contact material code. 2 Values, P for platinum and S for stainless steel.

$Y_{3-4}$= The contact spacing code. Values range from 00 - 99. At the present time, codes 00-20

indicate the spacing, in mm, from the centre of one contact to the centre of the other. For values from 0-20mm all spacings are uniform. For numbers above 20 the spacings are variable.

$Y_5$ = The sterility status code. X for sterile.

$Z_1$ = The body shape code. Values range from A - Z & 0-9.

$Z_{2-3}$ = Additional non-significant options. Values range from 00-99, A0-Z9 & AA-ZZ.

- Electrode body options, such as curvature
- Tail options including where it comes out of the body of the electrode, the angle of exit, whether it exits at the top or bottom, length of the tail (shorter or longer)
- Marker options

First Issued: **2003-12-12** Date: **2020-03-04** Expiry Date: **2024-05-26**

...making excellence a habit.™

# EC Design-Examination Certificate

**Supplementary Information to CE 77819**

Issued To:

**Ad-Tech Medical**
**Instrument Corporation**
**400 West Oakview Parkway**
**Oak Creek**
**Wisconsin**
**53154**
**USA**

# Certificate History

| Date | Reference Number | Action |
|---|---|---|
| 26 November 2003 | 1005 2662 | Transfer from another Notified Body. |
| 04 August 2004 | 1005 9995 | New Model Numbering system. |
| 18 November 2004 | 1006 1982 | 5 year Certificate renewal. |
| 02 November 2009 | 10110274 | Certificate renewal. Removal of table of old model numbers. Modification of $Y_1$ contact shape code range to A-N and S. |
| 08 May 2014 | 10145019 | Addendum - Removal of models with the X1-2 prefix codes QS, US, EG and QG. |
| 24 November 2014 | 10146956 | Certificate Renewal. Removal of model with the X1-2 code QD. |
| 09 December 2016 | 10164507 | DuPont Tyvek Medical Transition Project Update.<br>Removal of Product Codes: Strip Electrodes, Values: AS, BS, VS, WS and YS. Y5 = The sterility status code,: Non-Sterile. |
| 14 February 2018 | 8863716 | Change of address from: 1901 William Street, Racine, Wisconsin, 53404, USA; to: 400 West Oakview Parkway, Oak Creek, Wisconsin, 53154, USA. |

First Issued: **2003-12-12** Date: **2020-03-04** Expiry Date: **2024-05-26**

# EC Design-Examination Certificate

**Supplementary Information to CE 77819**

Issued To:

**Ad-Tech Medical**
**Instrument Corporation**
**400 West Oakview Parkway**
**Oak Creek**
**Wisconsin**
**53154**
**USA**

| Date | Reference Number | Action |
|---|---|---|
| 13 February 2019 | 7780740 | Traceable to NB 0086. |
| 01 October 2019 | 3043569 | Addendum - Addition of Sterigenics US, LLC (Queensbury site) for ETO sterilization using chamber 8, Cycle 280 |
| Current | 3043573 | Certificate Renewal. |

First Issued: **2003-12-12** Date: **2020-03-04** Expiry Date: **2024-05-26**

...making excellence a habit.™