

TCB APPLICATION FORM 731

To be completed by Eurofins Product Service GmbH

G0M20810-2039 Rev1.9 2008-11-14 DE Order Number:

Applicant's complete, legal business name: BIOTRONIK SE & Co. KG Item 1.

Applicant's FCC Registration Number (FRN): 0008008591

Item 2. Address Line 1: Woermannkehre 1

Address Line 2:

P.O. Box 470255

City: Berlin

State Zip/Postal Code: 12359 Country: Germany n/a

EPC (Equipment Product Code, Item 3.

FCC ID Grantee Code: max. 14 characters): PRIMUS

TCB Contact Information: n/a Item 4.

All questions regarding the application will be directed to this contact.

The original grant and invoice will be sent to this contact.

Item 5. TCB Scope:

A1: Unlicensed Radio Frequency Devices - Low power transmitters operating on frequencies below 1 GHz A2: Unlicensed Radio Frequency Devices - Low power transmitters operating on frequencies above 1 GHz, with the exception of spread spectrum devices

A3: Unlicensed Radio Frequency Devices - Unlicensed Personal Communication System (PCS) devices

A4: Unlicensed National Information Infrastructure (UNII) devices and low power transmitters using spread spectrum techniques B1: Licensed Radio Service Equipment - Personal Mobile Radio Services in 47 CFR Parts 22 (cellular), 24, 25, 26, and 27

B2: Licensed Radio Service Equipment -General Mobile Radio Services in the following 47 CFR Parts 22 (non-cellular), 74, 90, 95 and 97

B3: Licensed Radio Service Equipment -Maritime and Aviation Radio Services in 47 CFR Parts 80 and 87
B4: Licensed Radio Service Equipment -Microwave Radio Services in 47 CFR Parts 21, 74 and 101

C1: Telephone Terminal Equipment (47 CFR Part 68)

Item 5. Person at the applicant's address to receive grant or for contact:

> First Name: Gunnar Middle Initials: Last Name: Boersch

Title: Team Manager Regulatory Affairs Mail Stop:

Phone: +49-30-68905 EXT: - 1213 Fax: +49-30-68905-1921

E-mail: gunnar.boersch@biotronik.com

**Technical Contact:** Item 6.

> Company Name: Micro Systems Engineering, Inc

First Name: Middle Initials: Last Name: Stadnik Paul

6024 SW Jean Rd. Address Line 1

Address Line 2:

P.O. Box City: Lake Oswego

State: Zip/Postal Code: 97035 Country: USA Oregon

Phone: (503) 635-4016 x1011 Fax: (503) 635-9610

paul.stadnik@biotronik.com E-mail:

Item 7. Non-Technical Contact:

Company Name: Biotronik USA, Inc.

First Name: Jim

Address Line 1 6024 SW Jean Rd.

Address Line 2:

P.O. Box City: Lake Oswego

Zip/Postal Code: 97035 Country: USA State: Oregon

Phone: (503) 635-4016 x2640 Fax:

jim.horton@biotronikusa.com E-mail:

Primus 731Form 951.doc 02

Middle Initials:

Last Name: Horton

| Item 8.         | Confidentiality Request:  (a) Does this application include a request for confidentiality for any portion(s) of the data contained in this application pursuant to 47 CFR § 0.459 of the Commission Rules?   |                  |             |  |  |  |  |
|-----------------|--|------------------|-------------|--|--|--|--|
|                 | (b) Does short-term confidentiality apply to this application?  If yes, specify the short-term confidentiality release date:   | ☐ Yes<br>MM/DD/Y | ⊠ No<br>YYY |  |  |  |  |
| <u>ltem 9.</u>  | Related OET KnowledgeDataBase (KDB) Inquiry:   |                  |             |  |  |  |  |
|                 | Is there a KDB inquiry associated with this application? If so, enter the inquiry tracking number:   | ☐ Yes            | ⊠ No        |  |  |  |  |
| <u>Item 10.</u> | Modular Approval: Is this application for modular approval? If "Yes", please submit a cover letter addressing the modular approval requirements of DA 00-1407.  Modular Type:  | Yes              | ⊠ No        |  |  |  |  |
| <u>Item 11.</u> | Software Defined Radio Authorization:  |                  |             |  |  |  |  |
| 100             | Is this application for software defined radio authorization?  | ☐ Yes            | ⊠ No        |  |  |  |  |
| 11 40           |  |                  |             |  |  |  |  |
| <u>Item 12.</u> | Equipment Class: TNT  Description of product as it is marketed: PRIMUS (aka EVIA or ENTOVIS) family of implantable pacemakers  |                  |             |  |  |  |  |
| <u>Item 13.</u> | Application Purpose::  ☐ Change in identification of presently authorized equipment: ☐ Change in identification of presently authorized equipment: ☐ Original FCC ID: Grant date (MM/DD: ☐ Class II permissive change or modification of presently authorized  |                  | ipment      |  |  |  |  |
| <u>Item 14.</u> | Composite / Related Equipment:  Is the equipment in this application:  (a) a composite device subject to an additional equipment authorization?  (b) part of a system that operates with, or is marketed with, another device that requires an equipment authorization?  If either of the above questions is answered "Yes", please complete section 13(c).  (c) The related application:  has been granted under the FCC ID(s) listed to the right is in the process of being filed under the FCC ID(s) listed to the right is pending with the FCC under the FCC ID(s) listed to the right has a mix of pending and granted statuses under the FCC ID8s) to the right: |                  |             |  |  |  |  |
| <u>Item 15.</u> | Test Firm Information:   |                  |             |  |  |  |  |
| item 13.        | Name of test firm and contact person on file with the FCC, if different from applicant or contact person Company Name:  Address:  Storkower Str. 38c  City:  Reichenw  Germany  Phone:  +49 33631 888-200  Fax: +49 33631 888-640  E-Mail: j   | mermann<br>valde | nn@eurofin  |  |  |  |  |
| <u>Item 16.</u> | Grant Comments:  |                  |             |  |  |  |  |
|                 | Note: Text will appear at the bottom of the Grant of Equipment Authorization.  |                  |             |  |  |  |  |

| Item 17.   | Equipment Specifications  | 3:  |  |  |  |  |  |  |
|--|---|---|--|--|--|--|--|--|
| Frequenc   |   | Frequency   | <b>Emission Designat</b>   | or Microprocesso   | r FCC Grant  |  |  |  |
| in M   | , ,   | tolerance   | (See 47 CFR 2.201  |  |  |  |  |  |
|  | IN WATTS  | %, Hz, ppm  | •  |  | Part   |  |  |  |
| 400  | the second second   | [ SE ]  | Annual Control of the |  | Transmit Transmit  |  |  |  |
| 1402   | 405 1.4E-7  | [1.95] [ppm]  | 182KF1D  |  | 95I IT   |  |  |  |
|  |   |   |  |  |  |  |  |  |
| -  |   |   | -  | <del>}</del>   |  |  |  |  |
|  |   |   |  |  |  |  |  |  |
| For submi  | ssion of further line items, pl   | ease attach a separat   | e equipment specificat   | ions chart.  |  |  |  |  |
|  |   |   |  |  |  |  |  |  |
| Item 18. Equipment Authorization Waiver:                                     |   |   |  |  |  |  |  |  |
| Is there an equipment authorization waiver associated with this application? |   |   |  |  |  |  |  |  |
|  | If yes, has the associated  |   |  |  | ☐ Yes ☐ No   |  |  |  |
|  | ii yes, has the associated t  | valvoi booli appiovod   | and an information up  | loudou.  | _ 100 _ 110  |  |  |  |
|  |   |   |  |  |  |  |  |  |
| Pond one   | h certification carefully be  | ore answering and s   | cianina this application   | n  |  |  |  |  |
|  |   |   |  |  | DV FINE AND  |  |  |  |
|  | . FALSE STATEMEN  |   |  |  |  |  |  |  |
|  | NMENT (U.S. CODE, T   |   |  |  |  |  |  |  |
| LICENSE  | OR CONSTRUCTION   | I PERMIT (U.S.  | CODE, TITLE 47   | , SECTION 312  | (a)(1)), AND/OR  |  |  |  |
| FORFEIT  | URE (U.S. CODE, TITLE   | 47, SECTION 503   | ).   |  |  |  |  |  |
|  |   |   |  | Annual transport to the second |  |  |  |  |
| Item 19.   | SECTION 5301 (ANTI-DR   | IG ARUSE) CERTIE  | CATION   |  |  |  |  |  |
| itelli 13.   | The applicant must certify  |   |  | the application is su  | hight to a donial of   |  |  |  |
|  |   |   |  |  |  |  |  |  |
|  | Federal benefits, that inclu  |   |  |  |  |  |  |  |
|  | U.S.C. § 862 because of   |   |  | of a controlled subst  | ance. See 47 CFR   |  |  |  |
|  | 1.2002(b) for the definition  |   | · ·  |  |  |  |  |  |
|  | Does the applicant or author  | orized agent so certify   | ?  |  | Yes □ No   |  |  |  |
|  |   |   |  |  |  |  |  |  |
| Item 20.   | APPLICANT/AGENT CERTIF  | ICATION:  |  |  |  |  |  |  |
| Itom 20.   |   |   | II of the statements here  | in and the exhibits atta   | ched hereto, are true  |  |  |  |
|  | I certify that I am authorized to sign this application. All of the statements herein and the exhibits attached hereto, are true and correct to the best of my knowledge and belief. IN accepting a Grant of Equipment Authorization as a result of the representations made in this application, the applicant is responsible for (1) labeling the equipment with the exact FCC ID |   |  |  |  |  |  |  |
|  |   |   |  |  |  |  |  |  |
|  | specified in this application, (2   | 2) compliance statemen  | t labeling pursuant to the   | applicable rules, and  | (3) compliance of the  |  |  |  |
|  | equipment with the applicable   | technical rules. If the a   | pplicant is not the actual   | manufacturer of the ed   | quipment, appropriate  |  |  |  |
|  | arrangements have been ma   |   | er to ensure that produc   | tion units of this equip   | ment will continue to  |  |  |  |
|  | comply with the FCC's technic   |   |  |  |  |  |  |  |
|  | Authorizing an agent to sign  |   | solely at the applicant's  | discretion; however, t   | he applicant remains   |  |  |  |
|  | responsible for all statements  | n this application.   |  |  |  |  |  |  |
|  | If an agent has signed this ap  | plication on behalf of the  | e applicant, a written lette   | r of authorization which   | n includes information   |  |  |  |
|  | to enable the agent to respon   |   |  |  |  |  |  |  |
|  | the applicant. It is understood   | that the letter of authori  | zation must be submitted   |  |  |  |  |  |
|  | reserves the right to contact th  | e applicant directly at ar  | y time.  |  |  |  |  |  |
|  | i i   |   |  |  |  |  |  |  |
|  |   |   |  |  |  |  |  |  |
|  |   |   | )  |  |  |  |  |  |
| Signatur   | e of authorized applicant:  | 7/  |  |  |  |  |  |  |
|  |   |   | -  |  | 8  |  |  |  |
|  |   | ( ). (  |  |  | 35   |  |  |  |
| Title of au  | thorized signature  | Jens Zimmermann   | , Head of EIIC   | . & Radio Lat  |  |  |  |  |
| -  |   | NAME OF THE OWNER, OF THE OWNER, OF THE OWNER, |  |  | THE RESERVE AND ASSESSMENT OF THE PARTY OF T |  |  |  |
|  |   |   |  |  |  |  |  |  |
| Complete   | items below if an agent si  | gns the application   |  |  | 144  |  |  |  |
|  | Company Name:   | O   |  |  |  |  |  |  |
|  | First Name:   | Midd  | le Initials:   | Last Name:   | 42   |  |  |  |
|  | Address Line 1  | wiidd   | .otiaio.   | _uot Hullio.   | 77   |  |  |  |
|  |   |   |  |  |  |  |  |  |
|  | Address Line 2:   |   | City   |  |  |  |  |  |
|  | P.O. Box  | 71 /5   | City:  | 0  |  |  |  |  |
|  | State:  | ∠ıp/Pos   | stal Code:   | Country:   | **   |  |  |  |
|  | Phone:  |   | Fax  | :  |  |  |  |  |
|  | F-Mail:   |   |  |  |  |  |  |  |

Note: This form must be completed and provided with the submission.