FCC ID Labeling Scheme

Per 47 CFR 2.926 (e),

> "Where it is shown that a permanently affixed nameplate is not desirable or is not feasible, an alternative method of positively identifying the equipment may be used if approved by the Commission. The proposed alternative method of identification and the justification for its use must be included with the application for equipment authorization.
>
> Note: As an example, a device intended to be implanted within the body of a test animal or person would probably require an alternate method of identification."

Since the EUT is implanted in the human body, the FCC ID will not be applied to outside of the device. Instead, the applicant is proposing the following alternate method of applying the FCC ID number to two locations:

1. The FCC ID, along with the disclosure statement required by 95.1215(a), is in the User Manual (page 103 of the Lexos – see excerpt below).
2. The FCC ID also appears on the package label (see examples below), which is affixed to outside of the shipping box for the EUT.

Federal Communications Commission Disclosure

The Lexos VR-T/DR-T is equipped with an RF transmitter for wireless communications. This transmitter is authorized by rule under the Medical Implant Communications Service (47 CFR Part 95) and must not cause harmful interference to stations operating in the 400.150 - 406.000 MHz band in the Meteorological Aids (i.e., transmitters and receivers used to communicate weather data), the Meteorological Satellite, or the Earth Exploration Satellite Services and must accept interference that may be caused by such aids, including interference that may cause undesired operation. This transmitter shall be used only in accordance with the FCC Rules governing the Medical Implant Communications Service. Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this transmitter will be free from interference.

The FCC ID number for this device is: PG6LEXOS-T.

Lexos DR-T

Implantable Cardioverter Defibrillator
DDDRD, 2 x IS-1/BI, 2 x DF-1

Order No.: XXX XXX
Serial No.: **12345678**
Use Before: **99/99/9999**

DESCRIPTION: One dual chamber active housing implantable cardioverter defibrillator with two IS-1 connector receptacles and two DF-1 connector receptacles. Lexos DR-T contains Biotronik's Home Monitoring capabilities.

Programmable Parameters*	Factory Settings
Bradycardia Mode	**OFF**
Tachycardia Detection	**OFF**
Home Monitoring	**OFF**

CAUTION: When Shipped, all tachycardia and bradycardia functions are inactive!

*See technical manual for detailed specifications.

STERILE: Cardioverter Defibrillator as identified and accessories

NON-STERILE: Package inserts (documentation), refer to technical manual for additional information.

STERILIZATION: This unit has been gas sterilized with ethylene oxide. Sterility cannot be guaranteed if the package has been damaged during transportation. Please examine the package carefully before opening. If it shows any evidence of damage or mishandling, it should be returned immediately to BIOTRONIK. Once the box seal has been broken, title passes to the hospital and a purchase order is required.

CAUTION: Recommended Storage Temperature: 5° C - 55° C (41° F - 131° F).

CAUTION: ICD and lead systems which do not expressly claim to agree with the IS-1 or DF-1 dimensions generally have to be regarded as incompatible with IS-1 or DF-1 connectors. Consult your BIOTRONIK representative regarding lead-generator compatibility prior to the implantation of an ICD system.

CAUTION: Federal (U.S.A.) law restricts this device to sale by, or on the order of, a physician.

FCC Statement: Lexos DR-T is equipped with an RF transmitter for wireless communications. This device must not interfere with stations operating in the 400.150 - 406.000 MHz band in the Meteorological Satellite or Earth Exploration Satellite Services and must accept any interference received, including interference that may cause undesired operation.

Made in Germany

B1157-A 11/02

Lexos VR-T

Implantable Cardioverter Defibrillator
VVIRD, IS-1/BI, 2 x DF-1

Order No.: XXX XXX
Serial No.: **12345678**
Use Before: **99/99/9999**

DEVICE DESCRIPTION: One single chamber, rate adaptive implantable cardioverter defibrillator with active housing and with one IS-1 connector receptacle and two DF-1 connector receptacles. Lexos VR-T contains Biotronik's Home Monitoring capabilities.

Programmable Parameters*	Factory Settings
Bradycardia Mode	**OFF**
Tachycardia Detection	**OFF**
Home Monitoring	**OFF**

CAUTION: When shipped, all tachycardia and bradycardia functions are inactive!

*See technical manual for detailed specifications.

STERILE: Cardioverter Defibrillator as identified and accessories

NON-STERILE: Package inserts (documentation), refer to technical manual for additional information.

STERILIZATION: This unit has been gas sterilized with ethylene oxide. Sterility cannot be guaranteed if the package has been damaged during transportation. Please examine the package carefully before opening. If it shows any evidence of damage or mishandling, it should be returned immediately to BIOTRONIK. Once the box seal has been broken, title passes to the hospital and a purchase order is required.

CAUTION: Recommended Storage Temperature: 5° C - 55° C (41° F - 131° F).

CAUTION: ICD and lead systems which do not expressly claim to agree with the IS-1 or DF-1 dimensions generally have to be regarded as incompatible with IS-1 or DF-1 connectors. Consult your BIOTRONIK representative regarding lead-generator compatibility prior to the implantation of an ICD system.

CAUTION: Federal (U.S.A.) law restricts this device to sale by, or on the order of, a physician.

FCC Statement: (FCC ID PG6LEXOS-T) Lexos VR-T is equipped with an RF transmitter for wireless communications. This device must not interfere with stations operating in the 400.150 - 406.000 MHz band in the Meteorological Satellite or Earth Exploration Satellite Services and must accept any interference received, including interference that may cause undesired operation.

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