

**BUREAU OF INDIAN STANDARDS**

**(Faridabad Branch Office)**

**Our Ref:** FRBO/A-95001394

11.10.2021

FRBO has received an application from Switz Neubio India Private Limited under Option-1 for grant of licence to use of BIS standard mark on the product Implants for surgery - Active implantable medical devices: Part 7 particular requirements for cochlear implant systems as per IS/ISO 14708 : PART 7 : 2013.

As per the information obtained from BIS Website/ Intranet, Circulars of CMD's to ROs/ BOs the following is observed:

1. No BIS licence exists for the above mentioned product.
2. Marking fee, SIT & Grouping guidelines are not available for the product.
3. No test facility exists at BIS laboratory, OSL lab.

In the view of above, the application may be considered to be All India First for the above product.

CMD-2 is requested to provide relevant grouping guidelines, SIT, Marking fee, or any other information, if any, prevailing for this product.

All ROs and BOs are requested to send information regarding the above product by mail with respect to any application pending at their end or any other information which may be helpful to process this application.

All labs/ LPPD is requested to confirm the availability of testing facilities & testing charges as per IS/ISO 14708 : PART 7:2013.

-sd-

Ajay Kumar Soni  
Scientist - B

**Head (FRBO)**

**DDGN**

**Head (CMD-2)**

**Head (LPPD)**

**All RO's & BO's**

**ITSD- For circulation on intranet**

**(Kind Attention to ITS- Letter Added in Add Circular on BIS Intranet)**