



HANIL-TM CO., LTD.  
107-2 Donghwagongdan-ro, Munmak, Wonju, Gangwon, 26365 Republic of Korea  
TEL +82 33 8122020 FAX +82 33 7430087 EMAIL trade@haniltm.kr

February 24, 2022

## Declaration of Conformity



GIÁM ĐỐC

*Nguyễn Hồng Nga*

Manufacturer : HANIL-TM CO., LTD.  
Address : 107-2 Donghwagongdan-ro, Munmak-eup, Wonju-si,  
Gangwon-do, Republic of Korea  
Registered No. : Manufacturer 462

### Product Designation

Product License No. : 05-333  
Classification : Traction unit, electrically-powered  
Model : HT-101 Biotrack

Product License No. : 02-408  
Classification : Traction unit, electrically-powered  
Model : HT-102 Biotrack

Product License No. : 14-546  
Classification : Low frequency electric stimulator  
Model : BM-420

Product License No. : 05-333  
Classification : Low frequency electric stimulator  
Model : H-3000

Product License No. : 15-581  
Classification : Transducer assembly, ultrasound, therapeutic, diathermy  
Model : HS-502

Product License No. : 03-225  
Classification : Electric neuromuscular stimulator  
Model : Biomix HSP-601



Product License No. : 13-1841  
Classification : Acupuncture electrical stimulator  
Model : HA-306

Product License No. : 03-21  
Classification : Diathermy treatment system, microwave  
Model : HM-801

Product License No. : 04-1026  
Classification : Stimulator, microwave, interference  
Model : H-401

Product License No. : 04-1159  
Classification : Stimulator, microwave, interference  
Model : H-402

We, herewith declare that the product identified above has been registered under Law of Medical Device Act and meets the provisions of the Ministry of Food and Drug Safety (MFDS) Standard of Medical Devices.

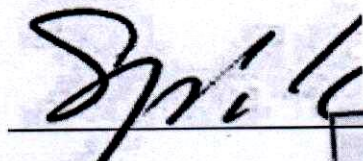
Standards applicable to this product are

Electric/Mechanical : MFDS Notification No. IEC 601-1(1988) 7,15, 19, 20, 42  
Safety Evaluation : MFDS Notification No. IEC 601-1(1988) 16, 21, 23, 49, 56, 57  
Electromagnetic : MFDS Notification No. 1997-43  
Susceptibility Test :

Certificated Body : Korea Testing Certification Institute (KTC)

And, the product identified above complies with the essential requirements of the standard : ISO 13485:2016 for design and development, production, sales and service of the medical devices identified above.

For and on behalf of,  
HANIL-TM CO., LTD.



Sung ho KIM  
Quality Assurance Manager

