

**Please insert your letterhead**

**DECLARATION**

We undersigned Suzhou Hongsheng Co., Ltd., with head office addressed in SOHO Vibrant City, Changshu, Suzhou City, Jiangsu Province, China, declares under its own full liability that those products:

Description	Model and/or code
Eye, 6x Life Size, 6 Parts	A660
Right Ear Structure Magnified Model, 3x Life Size, 3 Parts	A670
Right Ear Structure Magnified Model, 3x Life Size, 5 Parts	A671
Classic Heart, Life Size, 2 Parts	A400
Giant Heart, 3x Life Size, 3 Parts	A410
Classic Life Size Human Skeleton, 170 cm	A101
Life Size Human Skeleton W/ Muscle Origins and Insertions, Numbered, 170 cm	A102
Flexible Spine W/ Femur Heads, 85 cm	A121
Shoulder Joint Model W/ Functional Ligaments, Life Size	A201
Knee Joint W/ Functional Ligaments, Life Size	A202
Classic Human Skull Model, Life Size, 3 Parts	A150
Human Skull Model W/ Muscle Insertions & Origins, Numbered, Life Size, 3 Parts	A151
Didactic Painted Human Skull Model, Life Size, 3 Parts	A153
Giant Dental Care Model W/ Enlarged Toothbrush, 3x Life Size	A520

are not medical devices according to the medical device definition contained in the Medical Device Regulation (EU) 2017/745 and further amendments.

City Suzhou, data 18/10/2023

Company Suzhou Hongsheng Co., Ltd.

Person in charge/Name Herry Lee

Role / Position GM

Signature Herry Lee.