EC Declaration of Conformity

Manufacturers Name:

Audio Rhoon

Manufacturers Address:

Marskramer 17 3161ND Rhoon

Netherlands +31650574970

info@audiorhoon.nl

SRN (Single Registration Number):

NL-MF-000006073

Basic UDI-DI:

87193268503GROOVF9

Name of the Device (s):

GroovTube

Classification:

Class I

Conformity assessment route:

Audio Rhoon uses the following procedures for the CE-labeling of

their products according the Regulation MDR 2017/745:

<u>Class I:</u> EC conformity declaration according to annex IV + annex V

This declaration of conformity is issued under the sole responsibility of Audio Rhoon. We hereby declare that he medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices. This declaration is supported by a Quality System.

All supporting documentation is retained at the premises of the manufacturer.

Signature:

Place and date (dd.mm.yyyy) of issue:

Rhoon

9 - 6 - 2021

NAME Ruud van der Wel FUNCTION Owner

116/

AudioRhoon Marskramer 17 3161ND Rhoon Netherlands