G&H Wire Company, Inc.

July 27th 2020

To whom it may concern:

G&H Wire Company, d.b.a G&H Orthodontics does not provide any instructions for use. The Medical Device Directive 93/42 EEC, section 13.1 states that:

Each device must be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of the potential user and to identify the manufacturer.

This information comprises the details on the label and the data in the instruction for use. As far as practicable and appropriate, the information needed to use the device safely must be set out on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging. If individual packaging of each unit is not practicable, the information must be set out in the leaflet supplied with one or more devices.

Instructions for use must be included in the packaging for every device. By way of exception, no such instruction leaflet is needed for devices in Class I or Class IIa if they can be used completely safely without any such instructions.

Devices are well-established and are only sold to orthodontic professionals who are trained in the use of orthodontic devices.

Accordingly, G&H does not provide instructions for use.

Nichole Leahy-Glass
Global Regulatory Affairs Manager