



BTL Industries

EC DECLARATION OF CONFORMITY

Issued according to Annex II
to the Directive 93/42/EEC on Medical devices
as amended by the Directive 2007/47/EC

Manufacturer:

BTL Industries Limited
161 Cleveland Way
Stevenage
SG1 6BU, Hertfordshire
United Kingdom

Authorised Representative:

BTL ITALIA S.r.l.
Via San Leonardo 120
84131, Salerno
Italy

The **BTL Industries Limited** herewith declares under its sole responsibility that the product

Product Name:

BTL-08 Holter

Product Models:

**BTL-08 Holter H100
BTL-08 Holter H300
BTL-08 Holter H600**

Product Description:

Ambulatory ECG Holter monitor

Risk Classification:

Class IIa
According to Annex IX of MDD

is in conformity with requirements of Annex I to the Directive 93/42/EEC on Medical Devices as amended by the Directive 2007/47/EC

and bears the CE mark:



Notified Body:

DNV Product Assurance AS

EC Certificate No.:

11256-2017-CE-CZS-NA-PS

Date of Issue: May 24, 2021
Place of Issue: Stevenage

Signature on behalf of BTL Industries Ltd.

BTL Industries Limited
161 Cleveland Way
Stevenage
SG1 6BU Hertfordshire
United Kingdom

Jakub Machalek
Regulatory Affairs Manager

