



EU DECLARATION OF CONFORMITY

HEINE Optotechnik GmbH & Co. KG
Dornierstr. 6, 82205 Gilching
Germany

Single Registration Number: DE-MF-000006269

HEINE Headlights

We hereby declare, under sole responsibility, that the devices covered by the present EU declaration of conformity are in accordance with the MDR 2017/745.

The headlights consist of following combinations of

Product name	Basic UDI-DI	GMDN	UMDNS
ML4 LED	4053755_H_01_XB	46807	11-963
LoupeLight 2			
MicroLight 2			

and

Product name	Basic UDI-DI	GMDN	UMDNS
mPack	4053755_PP_01_97	--	16-337
mPack UNPLUGGED			
mPack mini			

The headlights are class I according to the risk classification of Annex VIII.



References to any common specifications: N/A

This declaration of conformity is valid until a revised declaration of conformity is issued.

HEINE OPTOTECHNIK
GmbH & Co. KG
Dornierstr. 6
82205 Gilching

Gilching, 10 June 2021
(Place and date of issue)


Thomas Sauerer / PRRC
(Name/function and signature)



ATITIKTIES DEKLARACIJA

Heine Optotechnik GmbH & CO. KG
Dornierstrasse 6
D-82205 Gilching, Vokietija

Registracijos Nr.: DE-MF-000006269

Mes pareiškiame, vienašališkos atsakomybės pagrindu, kad sekantys medicininiai prietaisai:
Šviesos

Grupė	Modelis	Basic UDI-DI	GMDN	UMDNS
Galviniai šviestuvai	ML4 LED	4053755_H_01_XB	46807	11-963
	LoupeLight 2			
	MicroLight 2			
	mPack	4053755_PP_01_97	--	16-337
	mPack UNPLUGGED			
	mPack mini			

kurie yra priskirti I klasei atitinka visoms nuostatomis apibrėžtoms direktyvoje 93/42/EEC pagal VIII priedą

CE

Ši atitikties deklaracija galioja iki naujos revizijos deklaracijos išleidimo dienos.

Gilching, 2021 birželio 10 d.

Thomas Sauerer / Kokybės direktorius