

EU-DECLARATION OF CONFORMITY

Manufacturer Wero Swiss Med Kft.
Ipartelep utca 6
4220 Hajdúböszörmény
Hungary

Single Registration Number: HU-MF-000006727

We declare under our sole responsibility that

the medical device
with Basic-UDI-DI (productcode)

NIKA-Lan Haft
76305236A814FD

Risk Class

class 1, unsterile
According to Annex VIII, Rule 1

meets all the provisions of the Regulation (EU) 2017 /745 which apply to it.

Applied harmonised standards, national
standards or other normative
documents

EN ISO 10993-1:2020
EN ISO 15223-1:2017
EN ISO 14971:2019


Conformity assessment procedure:

Regulation (EU) 2017/745
according to Annex IV

Place, date

Hajdúböszörmény, 30.06.2021

Name and function


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Tibor Balla, Head of Quality Management



Wero Swiss
Med Kft.
4220 Hajdúböszörmény Ipartelep utca 6.
Cégjegyzék: 09-09-029400
Adószám: 2690032-09