

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
76305236A26SG**

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


Tibor Balla, Head of Quality Management



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Med Kft.
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Regisztrált: 09-09-029406
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