Wero Swiss Med Kft.
Ipartelep utca 6
H-4220 Hajdúböszörmény
Hungary
www.weroswiss.com

EU-DECLARATION OF CONFORMITY

Manufacturer	Wero Swiss Med Kft. Ipartelep utca 6 4220 Hajdúböszörmény Hungary
Code of manufacturer:	HU-MF-000006727
the medical device with Basic-UDI-DI (productcode)	**Intermed Haft latexfrei** **76305236A91016E, 76305236A908579**
Risk Class	**class 1, unsterile**
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 route	Wero Swiss Med Kft. uses the following procedures for the CE-labeling of their products according the Regulation MDR 2017/745: Class 1: EC conformity declaration according to According to Annex VIII Rule 1 + Annex IX

This declaration of conformity is issued under the sole responsibility of Wero Swiss Med Kft.. We hereby declare that he medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices. This declaration is supported by the Quality System approval to ISO 13485:2016 issued by SGS Hungária Kft..
All supporting documentation is retained at the premises of the manufacturer.

Place, date	Hajdúböszörmény, 23.06.2021.
Name and function	..... Tibor Balla, Head of Quality Management