

Legal Manufacturer

Finess Hygiene AB Tolvmannavägen 1 59038 Kisa Sweden	www.finesshygiene.com Phone: +46 494 151 00 Mail: info@finesshygiene.com
- Single Registration Number (SRN)	SE-MF-000002970

Medical Device(s)

- Basic UDI-DI	7331246BAQN
- Product/trade name(s) and/or product code(s) (REF)/and or catalogue number	Disposable bibs and aprons
- Other ref. allowing identification (e.g. UDI-DI)	Appendix I
- Intended Purpose	The bibs and aprons are reducing the risk for contamination for healthcare professionals and user by absorbing leakage body liquids.
- Risk classification	Class I according to rule no. I in MDR annex VIII

Other information (if applicable)

- Common Specifications used for compliance	
- Notified Body name and identification no. and description of the conformity assessment procedure performed	
- Additional information	
- Standards used to assure compliance	Appendix II

The above mention manufacturer hereby declare that the above mentioned medical device(s) are compliant with the EU Regulation 2017/745 for Medical Devices and the EU legislations mentioned under "additional information".


This Declaration of Conformity is issued under the sole responsibility of the above mentioned manufacturer.

Name and Function:

Jörgen Pettersson, Quality Manager
Signature
Place and date of issue

Kisa, SE, 28.12.2021

 Finess Hygiene AB, Tolvmannavägen 1, 59038 Kisa,
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Appendix I, List of products

Art.no:	Product name:
60090	Bib with adhesive tape
60091	Bib with neck tie
60092	Bib with neck tie
60093	Bib with neck tie
60094	Bib with neck tie
60095	Bib with neck tie
65003	Bio Bib with adhesive tape
65004	Bio Bib with neck tie
65001	Bio Dental bib
65002	Bio Apron with tissue and film
60002	Apron with tissue and film
60004	Apron with tissue and film
60005	Apron with tissue and film
60006	Apron with tissue and film
65012	Bio Dental bib
81213	TE91 apron
81281	Dental bib
60097	Bib with adhesive tape
6500201	Bio Apron with tissue and film
6500203	Bio Apron with tissue and film
6500204	Bio Apron with tissue and film
6009003	Bib with adhesive tape
6500303	Bio Bib with adhesive tape

Appendix II, List of applicable standards used

No.	Document no.	Document title
1	MDR 2017/745	Medical Device Regulation (EU)
2	EN ISO 13485:2016	Medical Devices - Quality Management System
3	EN ISO 14971:2019	Medical Devices - Application of risk management to medical devices
4	EN ISO 15223-1:2016	Medical Devices - Symbols to be used with medical devices labels, labelling and information to be supplied
5	EN ISO 9001:2015	Quality Management System - requirements
6	EN ISO 14001:2015	Environmental Management Systems - Requirements with guidance for use
7	EN ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process