celltex
Since 1992

Declaration of conformity

Producer : **CELLTEX s.r.o.**

Address: Mokráň záhon 2, 821 04 Bratislava, Slovak republic

Product : Incontinence Pads

Class : Medical device class I

ART-NR		**UDI-DI**
AR 20100	Gesund Leben Einlagen Mini Plus	8588008398326
AR 20200	Gesund Leben Einlagen Normal	8588008398333
AR 20300	Gesund Leben Einlagen Extra	8588008398340
AR 20400	Gesund Leben Einlagen Super	8588008398357

Meet with harmonized standards:

- according to § 23 No. 56/2018 Coll. on product conformity assessment, making available of the product on the market and on change and amendment of some Acts

- according to Regulation (EU) 2017/745 of the European parliament and of the Council of 5 April 2017 on medical devices and fulfil the General requirements established in Annex I
The Devices shall achieve the performance intended by their manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose. They shall be safe and effective and shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art.

Applicable harmonized standards:

- Certificate ISO 9001:2015 Q-0760/21, valid to January 30th, 2023
- Regulation of the Government of the Slovak Republic n. 166/2020 Z.z. laying down details on technical requirements and conformity assessment procedures for medical devices

Medical Device is marked **CE**.
All documents including the technical documentation is kept by the manufacturer.

Authorised person: Ing. Michaela Chvojková

Quality manager
CELLTEX s.r.o.

CELLTEX s.r.o.
Mokráň záhon 2
821 04 Bratislava

Date: 15.06.2021
Bratislava