

ES PROHLÁŠENÍ O SHODĚ

vydané na výhradní odpovědnost výrobce

v souladu Regulation (EU) 2017/745 o zdravotnických prostředcích.

Výrobce: MAJOR CZ s.r.o.

Adresa: Lanškrounská 653/25, Předměstí, 568 02 Svitavy, Česká republika

tímto potvrzuje, že u zdravotnického prostředku:

Major Super Lux

posoudil shodu výrobku v souladu s čl. 11.2.b a přílohou V výše uvedené směrnice

a prohlašuje,

že vlastnosti zdravotnického prostředku splňují všechny požadavky stanovené výše zmíněnou směrnicí, a že je tento zdravotnický prostředek pro svůj určený účel použití bezpečný a účinný. Výrobce dále prohlašuje, že přijal opatření, kterými zabezpečuje shodu zdravotnických prostředků uváděných na trh se základními požadavky a technickou dokumentací výrobce.

Určený účel: Syntetické polymerní zuby pro zubní protézy.

Riziková třída: IIa podle pravidla 5 (příloha IX Regulation (EU) 2017/745).

K prokázání shody byly použity následující normy:

- ČSN EN ISO 13485:2016
- ČSN EN ISO 22112:2018
- ČSN EN ISO 14971:2020
- ČSN EN ISO 15223-1:2022
- ČSN EN ISO 20417:2021
- ČSN EN ISO 10993-1:2021

Notifikovaná osoba: DNV (NB 2460)

Číslo certifikátu: confirmation letter C633405

Platnost prohlášení: do 1.1.2028

Jménem výrobce ve Svitavách dne:18.11.2024



Petr Svatoš
jednatel



Notified Body Confirmation Letter Reference: C633405

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, DNV Product Assurance AS, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number NB 2460 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

MAJOR CZ s.r.o.
Lanškrounská 653/25
568 02 Svitavy
Czech Republic

SRN Number (if available):

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

Place and date:
Høvik, 2024/04/16



For the issuing office:
DNV Product Assurance AS – Notified Body 2460
Veritasveien 1, 1363 Høvik, Norway

André Fernandes
Management Representative

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer’s continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips, and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function.
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
MAJOR SUPER LUX, Type 1 (Anterior) MAJOR SUPER LUX, Type 2 (Posterior) BASIC UDI-DI: 8596527SUPER-LUXF8	Class IIa	MAJOR SUPER LUX	Certificate number: 108889-2017-CE-NOR-NE-PS NB number NB: 2460 Expiry date: 16 January 2023

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A			

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/04/16	C633405	Initial issue

Lack of fulfilment of conditions

The following may render this letter of confirmation invalid:

- Lack of compliance to the requirements of Regulation (EU) 2023/607.
- Significant changes to design or intended purpose of the devices.
- Changes in the quality system affecting production.
- Periodical audits not held within the timeframe.