

TÜV SÜD Product Service GmbH · Ridlerstraße 65 · 80339 München · Deutschland

Bauer-Walser AG Geschäftsbereich WBK Frau Dr. Andrea Pauling / QM Bunsenstraße 4-6 75210 Keltern Germany

Your Ref/Name 32345

Our Ref/Name PS-MHS-NA2-1

Lilia Tschalenko

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Fax

Date 2023-07-09 Page 1 von 4

Lilia.Tschalenko@tuvsud.com

Notified Body Confirmation Letter

Reference: 713270613

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, TÜV SÜD Product Service GmbH, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0123 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.

Bauer-Walser AG Bunsenstraße 4-6 75210 Keltern Germany

SRN Number: DE-MF000008160



The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below, see attachment:

- Table 1 identifies the devices which an MDR application has been received, written agreement concluded and for which the TÜV SÜD Product Service GmbH 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 TÜV SÜD Product Service GmbH has <u>not</u> 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 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that: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/AIMDD certificate expiry; or
- provided evidence that a competent authority of a Member State had granted a derogation in accordance with Article 59(1) of the MDR or
- provided evidence that a competent authority of a Member State had granted an exemption from the applicable conformity assessment procedure in accordance with Article 97(1) of the MDR respectively,

by the 20 Mar 2023 for the relevant devices.

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)

On behalf of the Notified Body,

TÜV SÜD Product Service GmbH Medical and Health Services

TÜV SÜD Product Service GmbH Medical and Health Services

Lilia Tschalenko

L. Tseliglenko

Conformity Assessment Responsible (CARE)

Julia Hoyer

Head of Certification Body - Deputy

9:14 GMT+2)



ATTACHMENT

Table 1: Devices covered by this letter and for which the TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive

Device name or Basic UDI-	MDR Device classification	If the MDR device is a sub-	MDD/AIMDD Certificate
DI (under MDR application)	(as proposed by the manu-	stitute device, identifica-	Reference(s) of the devices
	facturer and verified at the	tion of the corresponding	under MDR application,
	pre-/ application stage)	MDD/AIMDD device	and the NB Identification
Please see device list	□N/A	⊠ N/A	□ N/A
attached below			
	or	or	or
	☐ Class III	☐ Identification of the corre-	☐ Certification as follows:
	☐ Class IIb implantable non-	sponding device under	Certificate #1: G1 18 02
	WET device	MDD/AIMDD	32345 011
	☐ Class IIb excluding Class		NB#0123
	IIb implantable non-WET		
	⊠ Class IIa		
	☐ Class I devices placed on		or
	the market in sterile condition		
	☐ Class I devices with a		☐ N/A - Device did not re-
	measuring function		quire a Notified Body certifi-
	☐ Class I devices that qualify		cate under Directives
	as re-usable surgical instru-		
	ments		or
	☐ Class III implantable cus-		
	tom-made device		☐ Evidence that a competent
			authority of a Member State
			had granted acc. MDR,
			Art.59 (1) or Art.97 (1)
			Evidence #1; CA#
			Evidence #2; CA#

Table 2: Devices covered by this letter and for which the TÜV SÜD Product Service GmbH is <u>NOT</u> responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI- DI (under MDR application)	MDR Device classification (as proposed by the manu- facturer and verified at the pre-/ application stage)	If the MDR device is a sub- stitute device, identifica- tion of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A; all devices in scope are subject to Table 1.	⊠ N/A	⊠ N/A	⊠ N/A



Medical Device Name	Catalogue number	Basic UDI-DI	Classification
			
Jena 20 kt	4471	42519678AD20KTAB	class IIa
Jenador 11	467	42519678ADIN3HL	class Ila
Jenador 1	472	42519678AD20KTAB	class Ila
Jenador 1N	21947	42519678ADPCF10J4	class IIa
Jenador 1U	459	42519678ADH11EP	class IIa
Jenador 1P	458	42519678ADH5M8	class Ila
Jenador 31	468	42519678ADCFH1EP	class IIa
Jenador 41	469	42519678ADCFR1FM	class IIa
Jenador 51	22024	42519678ADCFR12GA	class Ila



Medical Device Name	Catalogue number	Basic UDI-DI	Classification
Jenador 71	470	42519678SIPAP40X4	class IIa
Jenadent 1G	12143	42519678AD1000NB35	class IIa
Jenadent 11	455	42519678ACHVGK6	class IIa
Jenadent 21	456	42519678ACHWTILN	class IIa
Jenapall B	473	42519678PCS31MJ	class IIa
Jenapall C	474	42519678PCP3QY	class IIa
Jenapall D	475	42519678PCG6QB	class IIa
Jenalot 960	310	42519678LAC960EL	class IIa
Jenalot 880	480	42519678LAC880PCKQ	class IIa
Jenalot 850	482	42519678LADH850J2	class Ila
Jenalot 800	483	42519678LADH800HK	class IIa
Jenalot 750	484	42519678LADH750HV	class IIa
Jenalot 710	479	42519678LAC710DT	class IIa
Jenadentlot 1120	490	42519678LAC1120BH	class IIa
Jenadentlot 1060	489	42519678LAC1060WEU	class IIa
Jenadentlot 1040	481	42519678LAC1040PE4	class IIa
Stahlgoldlot 930	487	42519678LSTG930WL	class IIa
FlexiGold 4	21815	42519678ACBOCHB	class IIa
FlexiGold ECO	21811	42519678ADCFR12GA	class lla
FlexiGold H	21810	42519678ACHG5GP	class IIa
FlexiGold Inlay	21814	42519678ADINHJU	class IIa
FlexiGold M	21809	42519678ADH7MC	class IIa
FlexiGold Supra	21807	42519678ADH31EV	class IIa
FlexiGold UniP	21808	42519678SIPAGASYX	class IIa
FlexiLot 700PF	21866	42519678LAC700PFHT	class IIa
FlexiLot 880 PF	21868	42519678LAC880PFKW	class IIa
Flexilot 920	21869	42519678LAC920E8	class IIa
FlexiLot 1020	21864	42519678LAC920E8	class IIa
Jenadent 21 Laserdraht	10283	42519678ACHWTILRC	class IIa
Jenador 1P Laserdraht	10282	42519678ADH5LGP	class IIa
Jenador 1U Laserdraht	10281	42519678ADH11LC8	class IIa
Jenador 41 Laserdraht	10139	42519678ADCFR1LHU	class IIa
Jenapall C Laserdraht	10280	42519678PCP3LNP	class IIa
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Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2023-07-09	713270613	Initial letter