27-Nov-2024

Extension of the Transitional Period for Medical Devices - Regulation (EU) 2023/607

To Whom It May Concern,

We are writing to inform you that, as outlined in EU Regulation 2023/607, the transitional periods for medical devices that currently comply with the Medical Device Directive 93/42/EEC was extended to allow continued supply of these devices into the EU market. Under this regulation, products can be legally placed on the market even if the corresponding CE Marking certificate has expired, so long as certain transitional provisions have been met.

We hereby certify, that, phenox GmbH, femtos GmbH and Wallaby Medical, Inc., have met the conditions set out in Article 120 of MDR as amended with Regulation (EU) 2023/607 and can declare that the CE Certificates issued are considered valid until the following dates after the expiration date on the certificate:

A. **31 December 2027**, for all class III devices, and for class IIb implantable devices:

Manufacturer phenox GmbH
a) p64 Flow Modulation Device
b) p64 MW (HPC) and p48 MW (HPC) Flow Modulation Device
c) pCONUS (HPC) and pCONUS 2 (HPC) Bifurcation Aneurysm Implant
d) pORTAL Steerable Hydrophilic Guidewire
e) pITA Rapid Exchange Neurovascular PTA Balloon Catheter
f) pNOVUS 21 Microcatheter
g) pHLO AC Aspiration Catheter
h) pRESET Thrombectomy Device (STANDARD, LITE & LUX)

Manufacturer femtos GmbH
a) pEGASUS Stent System
b) pRELAX - Vasospasm Treatment Device

Manufacturer Wallaby Medical Inc.
a) Wallaby Avenir Coil System

B. **31 December 2028**, for all other products including class I devices:

Manufacturer phenox GmbH
a) pDC Detachment Cable

All relevant documentation for all three legal manufacturers, listing all affected product families, are attached as Appendices to this document. This includes both the letter of confirmation from the applicable Notified Body and the Legal Manufacturer's Declaration.

For further information regarding the transition from MDD to MDR, a separate communication will be provided at a later date. If you have any questions, please contact us directly.

Sincerely

27-Nov-2024

Gary Brogan
Vice President of Global Regulatory and Clinical Affairs

References:
1. Extension of the MDR Transitional Period (Link)
2. Fact Sheet for authorities in non-EU/EEA states (Link)

Appendix 1

Legal Manufacturer

phenox GmbH

Affected product families.

a) p64 Flow Modulation Device
b) p64 MW (HPC) and p48 MW (HPC) Flow Modulation Device
c) pCONUS (HPC) and pCONUS 2 (HPC) Bifurcation Aneurysm Implant
d) pORTAL Steerable Hydrophilic Guidewire
e) pITA Rapid Exchange Neurovascular PTA Balloon Catheter
f) pNOVUS 21 Microcatheter
g) pHLO AC Aspiration Catheter
h) pRESET Thrombectomy Device (STANDARD, LITE & LUX)

DQS Medizinprodukte GmbH | August-Schanz-Str. 21 | 60433 Frankfurt am Main

phenox GmbH

Lise-Meitner-Allee 31
44801 Bochum
Germany

Date: 29.04.2024

Notified Body Confirmation Letter
Reference: 1000176093

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, DQS Medizinprodukte GmbH, a Notified Body designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0297 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:

phenox GmbH

Lise-Meitner-Allee 31
44801 Bochum
Germany

SRN: DE-MF-000006524

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables listed below: Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which DQS Medizinprodukte 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 DQS Medizinprodukte GmbH 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 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 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.

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,

Cristina Jung

Cristina Jung
Regulatory Affairs Manager

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 (as proposed by the manufacturer within the 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/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Neurovascular Flow Diverter p64 Flow Modulation Device Basis UDI-DI: 426012378FlowDiverterSV	Class III	p64 Flow Modulation Device	506681 MRA NB: 0297 345178 MR2
Neurovascular Flow Diverter p64 MW (HPC) Flow Modulation Device Basis UDI-DI: 426012378FlowDiverterSV	Class III	pFMD phenox Flow Modulation Device	547128 MRA NB: 0297 345178 MR2
Neurovascular Flow Diverter p48 MW (HPC) Flow Modulation Device Basis UDI-DI: 426012378FlowDiverterSV	Class III	p48 MW (HPC) Flow Modulation Device	539671 MRA NB: 0297 345178 MR2
Thrombectomy Systems pRESET STANDARD Thrombectomy Device Basis UDI-DI: 426012378ThrombectomyF6	Class III	pRESET Thrombectomy Device	495569 MRA NB: 0297 345178 MR2
Thrombectomy Systems pRESET LUX Thrombectomy Device Basis UDI-DI: 426012378ThrombectomyF6	Class III	pRESET Thrombectomy Device	495569 MRA NB: 0297 345178 MR2

Device name and Basic UDI-DI (as proposed by the manufacturer within the 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/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Thrombectomy Systems pRESET LITE Thrombectomy Device Basis UDI-DI: 426012378ThrombectomyF6	Class III	pRESET Thrombectomy Device	495569 MRA NB: 0297 345178 MR2
Bifurcation Aneurysm Implant pCONUS 2 (HPC) Bifurcation Aneurysm Implant Basis UDI-DI: 426012378BifurImplantGK	Class III	pCONUS Bifurcation Aneurysm Implant	508247 MRA NB: 0297 345178 MR2
Bifurcation Aneurysm Implant pCONUS (HPC) Bifurcation Aneurysm Implant Basis UDI-DI: 426012378BifurImplantGK	Class III	pCONUS Bifurcation Aneurysm Implant	508247 MRA NB: 0297 345178 MR2
Neurovascular Treatment Accessories pDC phenox Detachment Cable Basis UDI-DI: 426012378DetachementCabHN	Class I devices placed on the market in sterile condition	pDC phenox Detachment Cable	345178 MR2 Unique ID: 170772547 NB:0297 345178 MR2
pITA Rapid Exchange Neurovascular PTA Balloon Catheter Basis UDI-DI: 426012378pITAE6	Class III	pITA Rapid Exchange Neurovascular PTA Balloon Catheter	520194 MRA NB: 0297 345178 MR2

Device name and Basic UDI-DI (as proposed by the manufacturer within the 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/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
pORTAL Steerable Hydrophilic Guidewire Basis UDI-DI: 426012378GuideWire5C	Class III	pORTAL Steerable Hydrophilic Guidewire Basis	532346 MRA NB: 0297 345178 MR2
pHLO AC Aspiration Catheter Basis UDI-DI: 426012378AspirationCathJM	Class III	pHLO AC Aspiration	547740 MRA NB: 0297 345178 MR2
pNOVUS 21 Microcatheter Basis UDI-DI: 426012378Microcatheter2Q	Class III	pNOVUS 21 Microcatheter	546917 MRA NB: 0297 345178 MR2

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 (as proposed by the manufacturer within the 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/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
04.01.2024	1000156682	Initial issue
29.04.2024	1000176093	Addition of products

Phenox GmbH | Lise-Meitner-Allee 31 | D-44801 Bochum | Germany

Manufacturer's Declaration

in relation to **Regulation (EU) 2023/607** amending **Regulations (EU) 2017/745** as regards the transitional provisions for certain medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and*
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Phenox GmbH
Manufacturer address and contact details	Lise-Meitner-Alle 31 44801 Bochum, Germany
Single Registration Number (SRN)	DE-MF-000006524

Notified body name	DQS Medizinprodukte GmbH August-Schanz-Str. 21 60433 Frankfurt am Main Germany
Notified body number	0297
Directive Certificate number(s) to which this confirmation is made	See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	See attached schedule
End date of extended validity/transition period	See attached schedule

Phenox GmbH | Lise-Meitner-Allee 31 | D-44801 Bochum | Germany
Tel.+49 (0)234 36 919-0 | Fax +49 (0)234 36 919-19 | info@phenox.info | https://www.wallabyphenox.com/
Geschäftsführer: Yi Xing, James Edson Lago, Michael Nevin Alper, Bing Liu
HR 10388 Registergericht Bochum | Steuernummer 35057251074 | Ust-Id Nr. DE 814369033
Volksbank Bochum Witten eG IBAN: DE20 4306 0129 0124 1375 00 / BIC/SWIFT: GENODEM1BOC

Phenox GmbH | Lise-Meitner-Allee 31 | D-44801 Bochum | Germany

We, as the manufacturer declare under our sole responsibility:

- for the listed **Directive Certificates** (see attached schedule) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and*
- the listed devices in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

- **Directive Certificates** as listed in the attached schedule
  - Directive Certificates covering the listed devices were issued after 25 May 2017, were valid on 26 May 2021 and have not been withdrawn afterwards.
  - The certificate for p64 Flow Modulation expired *before* 20 March 2023. Before the original date of expiry as indicated on the Directive Certificate, we and the notified body have signed written agreements in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the devices covered by the expired certificates or in respect of a devices intended to substitute that device
  - Formal applications to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment have been made by us to a notified body for the devices listed in the attached schedule before 26 May 2024 and signed written agreements were in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

- **Quality Management System (QMS)**

  A QMS in accordance with Article 10(9) MDR is in place. The notified body has issued a certificate for the MDR-compliant QMS.

- **Device(s) as listed in the attached schedule**
  - The devices continue to comply with the MDD.
  - There are no significant changes in the design and intended purpose.
  - The devices do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

phenox GmbH, Bochum 2024-10-24

Dr. -Ing Christoph Welp
Person Responsible for Regulatory Compliance

Phenox GmbH | Lise-Meitner-Allee 31 | D-44801 Bochum | Germany
Tel.+49 (0)234 36 919-0 | Fax +49 (0)234 36 919-19 | info@phenox.info | https://www.wallabyphenox.com/
Geschäftsführer: Yi Xing, James Edson Lago, Michael Nevin Alper, Bing Liu
HR 10388 Registergericht Bochum | Steuernummer 35057251074 | Ust-Id Nr. DE 814369033
Volksbank Bochum Witten eG IBAN: DE20 4306 0129 0124 1375 00 / BIC/SWIFT: GENODEM1BOC

Phenox GmbH | Lise-Meitner-Allee 31 | D-44801 Bochum | Germany

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)	Directive Certificate number(s) to which this confirmation is made	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity	Notified Body name and number that issued the Directive Certificate	Notified Body name and number where the MDR application was lodged/contract signed	MDR Submission to NB for Technical Documentation Review	End date of extended validity / transition period	Substitute Device(s) (if applicable)
p64 Flow Modulation Device	345178 MR2 506681 MRA	2022-10-14	DQS Medizin-produkte GmbH NB: 0297	DQS Medizin-produkte GmbH NB: 0297 (FD3490)	Submitted 2022-02-11	2027-12-31	Neurovascular Flow Diverter Basis UDI-DI: 426012378FlowDiverterSV
pFMD phenox Flow Modulation Device	345178 MR2 547128 MRA	2024-05-26	DQS Medizin-produkte GmbH NB: 0297	DQS Medizin-produkte GmbH NB: 0297 (FD3490)	Submitted 2022-02-11	2027-12-31	Neurovascular Flow Diverter Basis UDI-DI: 426012378FlowDiverterSV
p48 MW (HPC) Flow Modulation Device	345178 MR2 539671 MRA	2024-05-26	DQS Medizin-produkte GmbH NB: 0297	DQS Medizin-produkte GmbH NB: 0297 (FD3490)	Submitted 2022-02-11	2027-12-31	Neurovascular Flow Diverter Basis UDI-DI: 426012378FlowDiverterSV
pRESET Thrombectomy Device	345178 MR2 495569 MRA	2024-05-26	DQS Medizin-produkte GmbH NB: 0297	DQS Medizin-produkte GmbH NB: 0297 (FD3643)	Submitted 2022-11-25	2027-12-31	Thrombectomy Systems Basis UDI-DI: 426012378ThrombectomyF6
pCONUS Bifurcation Aneurysm Implant	345178 MR2 508247 MRA	2024-05-26	DQS Medizin-produkte GmbH NB: 0297	DQS Medizin-produkte GmbH NB: 0297 (FD3885)	Submitted 2023-03-24	2027-12-31	Bifurcation Aneurysm Implant Basis UDI-DI: 426012378BifurImplantGK
pDC phenox Detachment Cable	345178 MR2	2024-05-26	DQS Medizin-produkte GmbH NB: 0297	DQS Medizin-produkte GmbH NB: 0297 (FD3909)	Submitted 2023-05-15	2028-12-31	pDC phenox Detachment Cable Basis UDI-DI: 426012378DetachementCabHN
pITA Rapid Exchange Neurovascular PTA Balloon Catheter	345178 MR2 520194 MRA	2024-05-26	DQS Medizin-produkte GmbH NB: 0297	DQS Medizin-produkte GmbH NB: 0297 (FD4046)	planned before 2026-12-31	2027-12-31	pITA Rapid Exchange Neurovascular PTA Balloon Catheter Catheter Basis UDI-DI: 426012378NeuroBallon38
pORTAL Steerable Hydrophilic Guidewire	345178 MR2 532346 MRA	2024-05-26	DQS Medizin-produkte GmbH NB: 0297	DQS Medizin-produkte GmbH NB: 0297 (FD4041)	planned before 2026-12-31	2027-12-31	pORTAL Steerable Hydrophilic Guidewire Basis Basis UDI-DI: 426012378GuideWire5C
pHLO AC Aspiration Catheter	345178 MR2 547740 MRA	2024-05-26	DQS Medizin-produkte GmbH NB: 0297	DQS Medizin-produkte GmbH NB: 0297 (FD4053)	planned before 2026-12-31	2027-12-31	pHLO AC Aspiration Catheter Basis UDI-DI: 426012378AspirationCathJM
pNOVUS 21 Microcatheter	345178 MR2 546917 MRA	2024-05-26	DQS Medizin-produkte GmbH NB: 0297	DQS Medizin-produkte GmbH NB: 0297 (FD4054)	planned before 2026-12-31	2027-12-31	pNOVUS 21 Microcatheter Basis UDI-DI: 426012378Microcatheter2Q

Phenox GmbH | Lise-Meitner-Allee 31 | D-44801 Bochum | Germany
Tel.+49 (0)234 36 919-0 | Fax +49 (0)234 36 919-19 | info@phenox.info | https://www.wallabyphenox.com/
Geschäftsführer: Yi Xing, James Edson Lago, Michael Nevin Alper, Bing Liu
HR 10388 Registergericht Bochum | Steuernummer 35057251074 | Ust-Id Nr. DE 814369033
Volksbank Bochum Witten eG IBAN: DE20 4306 0129 0124 1375 00 / BIC/SWIFT: GENODEM1BOC

Appendix 2

Legal Manufacturer

femtos GmbH

Affected product families.

a) pEGASUS Stent System
b) pRELAX – Vasospasm Treatment Device

femtos GmbH

Universitätsstraße 136
44799 Bochum
Germany

Date: 2024-10-07

Notified Body Confirmation Letter
Reference: 1000200512

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, DQS Medizinprodukte GmbH, a Notified Body designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0297 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:

femtos GmbH

Universitätsstraße 136
44799 Bochum
Germany

SRN: N/A

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables listed below: Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which DQS Medizinprodukte 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 DQS Medizinprodukte GmbH 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 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 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.
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,

Cristina Jung
Regulatory Affairs Manager

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 (as proposed by the manufacturer within the 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/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
pEGASUS Stent System (HPC)	Class III	N/A	549256 MRA (NB 0297)
pRELAX Vasospasm Treatment Device	Class III	N/A	523925 MRA (NB 0297)

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 (as proposed by the manufacturer within the 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/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023-12-05	1000151822	Initial issue
2024-10-04	1000200512	Korrektur der Zertifikatsreferenz für pRELAX

femtos GmbH | **Universitätsstraße** 136 | D-44799 Bochum | Germany

Manufacturer's Declaration

in relation to **Regulation (EU) 2023/607** amending **Regulations (EU) 2017/745** as regards the transitional provisions for certain medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	femtos GmbH
Manufacturer address and contact details	Universitätsstraße 136 44799 Bochum, Germany
Single Registration Number (SRN)	DE-MF-000005499

Notified body name	DQS Medizinprodukte GmbH August-Schanz-Str. 21 60433 Frankfurt am Main Germany
Notified body number	0297
Directive Certificate number(s) to which this confirmation is made	See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	See attached schedule
End date of extended validity/transition period	See attached schedule

femtos GmbH | **Universitätsstraße** 136 | D-44799 Bochum | Germany

We, as the manufacturer declare under our sole responsibility:

- for the listed **Directive Certificates** (see attached schedule) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met and
- the listed devices in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

- **Directive Certificates** as listed in the attached schedule
  - Directive Certificates covering the listed devices were issued after 25 May 2017, were valid on 26 May 2021 and have not been withdrawn afterwards.
  - Formal applications to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment have been made by us to a notified body for the devices listed in the attached schedule. Written agreements in accordance with section 4.3 subparagraph 2 of Annex VII of the MDR shall be signed by 26 September 2024.

- **Quality Management System (QMS)**
  A QMS in accordance with Article 10 (9) MDR is in place.

- **Device(s) as listed in the attached schedule**
  - The devices continue to comply with the MDD.
  - There are no significant changes in the design and intended purpose.
  - The devices do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

femtos GmbH, Bochum 2024-03-11

Attila Kravecz
Managing Director

femtos GmbH | Universitätsstr. 136 | 44799 Bochum | Germany
Tel.+49(0) 234 970 50 320 | femtos.info@wallabyphenox.com | www.phenox.net | femtos.de
Geschäftsführer: Attila Kravecz, Michael N. Alper | AG Bochum | HRB 15292
Volksbank Bochum Witten eG | IBAN DE98430601290136943200 | BIC GENODEM1BOC

femtos GmbH | **Universitätsstraße** 136 | D-44799 Bochum | Germany

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)	**Directive Certificate number(s) to which this confirmation is made**	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity**	**Notified Body name and number that issued the Directive Certificate**	**Notified Body name and number where the MDR application was lodged/contract signed**	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
pEGASUS Stent System (HPC)	549256 MRA	2024-05-26	DQS Medizin-produkte GmbH NB: 0297	DQS Medizin-produkte GmbH NB: 0297	2027-12-31	N/A
pRELAX Vasospasm Treatment Device	523925 MRA	2024-05-26	DQS Medizin-produkte GmbH NB: 0297	DQS Medizin-produkte GmbH NB: 0297	2027-12-31	N/A

femtos GmbH | Universitätsstr. 136 | 44799 Bochum | Germany
Tel.+49(0) 234 970 50 320 | femtos.info@wallabyphenox.com | www.phenox.net | femtos.de
Geschäftsführer: Attila Kravecz, Michael N. Alper | AG Bochum | HRB 15292
Volksbank Bochum Witten eG | IBAN DE98430601290136943200 | BIC GENODEM1BOC

Appendix 3

Legal Manufacturer

Wallaby Medical Inc.

Affected product families.

a) Wallaby Avenir Coil System

Wallaby Medical
22901 Mill Creek Drive
Laguna Hills
California
92653
USA

2024-03-27

Notified Body Confirmation Letter
Reference: EU2023-607/819705

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, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** 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:

Wallaby Medical
22901 Mill Creek Drive
Laguna Hills
California
92653
USA
SRN Number (if available): US-MF-000010241

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 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 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.

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 BSI Group The Netherlands B.V.,

Graeme Tunbridge
Senior Vice President, Medical Devices

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 or 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/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Wallaby Avenir Coil System	Class III	Not Applicable	#1 CE 684926, expiry date 2024-05-26; NB# 2797 #2 CE 684927, expiry date 2024-05-26; NB#2797

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 or 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/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	Action
2024/03/27	Initial issue

Wallaby Medical

Manufacturer's Declaration to Regulation (EU) 2023/607

According to Regulation (EU)2017/745 (MDR) and regarding the transitional provisions, Wallaby Medical declares the amendments to Article 120 of the MDR, as amended by Regulation (EU) 2023/607 applies to the following device(s):

Manufacturer name:	Wallaby Medical
Manufacturer address and contact details:	22901 Mill Creek Drive Laguna Hills California 92653 USA E-Mail: info.US@wallabyphenox.com
Single Registration Number (SRN) (if available):	US-MF-000010241

Authorised Representative name	Emergo Europe BV
Authorised Representative address and contact details	Westervoortsedijk 60 6827 AT, Arnhem THE NETHERLANDS
Single Registration Number (SRN)	NL-AR-000000116

Notified body name (if applicable)	■ See attached schedule
Notified body number (if applicable)	■ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	■ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	■ See attached schedule
End date of extended validity/transition period	■ See attached schedule

Wallaby Medical

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[1]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service, namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021, was/were not withdrawn by 20 March 2023
- *Choose applicable statements:*

☐ Expired *before* 20 March 2023:

☐ Before the original date of expiry as indicated on the Directive Certificate, we and the notified body have signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment in respect of the device covered by the expired certificate or in respect of a device intended to substitute that device

☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request)

☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

■ Expired/expires *after* 20 March 2023:

■ A formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its substitute and a signed written agreement is/will be in place

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

Wallaby Medical

in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

- **Up-classified devices**

  In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

  Choose one applicable statement:

  ☐ A formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its substitute and a signed written agreement is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

- **Quality Management System (QMS)**

  - *Choose one applicable statement:*

  ☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

  ■ A QMS in accordance with Article 10(9) MDR is in place.

  ☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

- **Device(s) as listed in the attached schedule**

  - The device(s) continue to comply with the AIMDD or MDD.
  - The device(s) has/have not been significantly changed in its/their design and intended purpose since 26 May 2021.
  - The device(s) do not present an unacceptable risk to health or safety of patients, users, or other persons, or to other aspects of the protection of public health.

Wallaby Medical
22901 Mill Creek Drive
Laguna Hills, California, 92653
USA

12 APR 2024

Nate Knock (VP of Global Quality) **Date**

Wallaby Medical

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Device identification *(e.g., device name, family / group name device model or catalogue number)*	**Directive Certificate number(s) to which this confirmation is made** □ *Not applicable*	**Original expiry date**[2] □ *Not applicable*	**Notified Body name and number** □ *Not applicable*	**Classification and rule under the MDR**	**End date of extended validity / transition period**	**Substitute Device** ■ *Not applicable*
Wallaby Avenir Coil System	**CE 684926** **CE 684927**	**2024-05-26**	**BSI Group The Netherlands B.V.** **Notified Body number: 2797**	**Class III and Rule 8 under MDR Annex VIII**	**2027-12-31**	

[2] As indicated on the Directive Certificate prior to the extension of the validity.