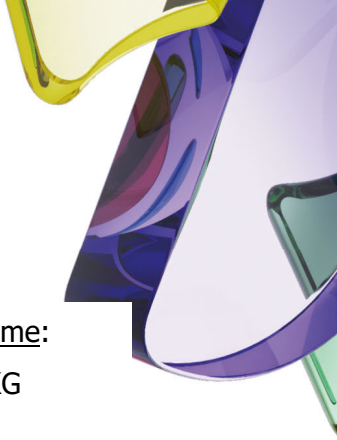

VYGON Germany GmbH
Prager Ring 100
Aachen Nordrhein-Westfalen
52070 Germany

Previous company name:
Vygon GmbH & Co. KG
Prager Ring 100
Aachen Nordrhein-Westfalen
52070 Germany

10-Jun-2025

Notified Body Confirmation Letter

Reference: EU2023-607/969561

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:

VYGON Germany GmbH
Prager Ring 100
Aachen Nordrhein-Westfalen
52070 Germany

Previous company name:
Vygon GmbH & Co. KG
Prager Ring 100
Aachen Nordrhein-Westfalen
52070 Germany

SRN Number (if available): DE-MF-000005305, DE-PR-000034160

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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
nutriline nutriline twinflo premicath	Class III	N/A	Certificate Z/17/04150E; NB0481 expiry 2022-12-19
multicath2 multicath3 multicath4 multicath5 multicath7	Class III	N/A	Certificate Z/17/04150E; NB0481 expiry 2022-12-19
lifecath broviac lifecath hickman lifecath biflux lifecath triple	Class III	N/A	Certificate Z/17/04150E; NB0481 expiry 2022-12-19 Certificate Z/16/03966E; NB0481 expiry 2021-11-15
repairsets lifecath	Class I device placed on the market in sterile condition	N/A	Certificate Z/17/04150E; NB0481 expiry 2022-12-19
silicone glue	Class I device placed on the market in sterile condition	N/A	Certificate Z/17/04150E; NB0481 expiry 2022-12-19
seldipur smartmidline	Class IIa	N/A	Certificate Z/17/04150E; NB0481 expiry 2022-12-19
leaderflex	Class III	N/A	Certificate Z/17/04150E; NB0481 expiry 2022-12-19
combcard vygocard	Class I device placed on the market in sterile condition	N/A	Certificate Z/17/04150E; NB0481 expiry 2022-12-19
lifecath PICC PUR lifecath PICC easy lifecath CT PICC easy	Class III	N/A	Certificate Z/17/04150E; NB0481 expiry 2022-12-19 Certificate Z/18/04325E; NB0481 expiry 2023-10-27 Certificate Z/20/04654E; NB0481 expiry 2021-05-22

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
epicutaneo cava epicutaneo2 epicutaneo cava pur	Class III	N/A	Certificate Z/17/04150E; NB0481 expiry 2022-12-19 Certificate Z/18/04202E; NB0481 expiry 2023-03-26
lifecath midline pur	Class IIb implantable non-WET	N/A	Certificate Z/17/04150E; NB 0481 expiry 2022-12-19 + Certificate Z/18/04325E; NB 0481 2023-10-27
dualysecath trilysecath	Class III	N/A	Certificate Z/17/04150E; NB0481 expiry 2022-12-19
umbilicalcath3	Class III	N/A	Certificate Z/17/04150E; NB0481 expiry 2022-12-19
bipacingball	Class III	N/A	Certificate Z/17/04150E; NB0481 expiry 2022-12-19 Certificate Z/19/04554E; NB0481 expiry 2024-06-05
microsite splitneedle peelable cannula introducath desilet	Class IIa	N/A	Certificate Z/17/04150E; NB0481 expiry 2022-12-19
desivalve	Class IIa	N/A	Certificate Z/17/04150E; NB0481 expiry 2022-12-19
leadercathexpert multicath3expert multicath2expert multicath4expert multicath5expert multicath7expert	Class III	N/A	Certificate Z/17/04150E; NB0481 expiry 2022-12-19
dualysecathexpert trilysecathexpert	Class III	N/A	Certificate Z/17/04150E; NB0481 expiry 2022-12-19
maxfloexpert	Class III	N/A	Certificate Z/17/04150E; NB 0481 expiry 2022-12-19 Certificate Z/18/04325E; NB 0481 expiry 2023-10-27

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
umbilicalcath expert umbilicalcath2 expert	Class III	N/A	Certificate Z/17/04150E; NB0481 expiry 2022-12-19
multistar2 multistar3 multistar4 multistar5 multistar7	Class III	N/A	Certificate Z/17/04150E; NB 0481 expiry 2022-12-19 Certificate Z/20/04710E; NB 0481 expiry 2023-10-27
premistar	Class III	N/A	Certificate Z/17/04150E; NB 0481 expiry 2022-12-19 Certificate Z/20/04710E; NB 0481 expiry 2023-10-27

Table 2: Devices covered by this letter and for which the NB 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 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
2024/10/07	Initial issue.
2024/10/09	Amended – Change 'Vygocard' to 'vygoncard'.
2024/11/27	Amended – Corrected certificate number references for lifecath midline pur, maxfloexpert, multistar series and premistar.
2025/01/09	Amended – Change of Legal Manufacturer name from Vygon GmbH & Co. KG to VYGON Germany GmbH.
2025/06/10	Amended - Included a reference to the previous company name.