POHL BOSKAMP

Manufacturer's Declaration

in relation to 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, 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.

We, the company

G. Pohl-Boskamp GmbH & Co. KG
Kieler Strasse 11
25551 Hohenlockstedt
Germany
Single Registration Number: DE-MF-000010001

declare on our own responsibility:

- for the Directive Certificates listed in the 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,

namely by fulfilling the following conditions:

- Directive Certificates covering the listed devices were issued after 25 May 2017 and were valid on 26 May 2021 and have not been withdrawn afterwards.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 for the listed devices and a signed written agreement is in place in accordance with Section 4.3, second subparagraph of Annex VII MDR.
- A quality management system in accordance with Article 10(9) MDR is in place.
- The devices listed in the attached schedule continue to comply with the MDD.
- There are no significant changes in the design and intended purpose.
- The devices listed in the attached schedule 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.

Hohenlockstedt, 10 April 2024

G. Pohl-Boskamp GmbH & Co. KG
POHL BOSKAMP
Pharmaceuticals since 1835
Kieler Str. 11 25551 Hohenlockstedt Germany

Lea Dornseiff
Lea Dornseiff
Advisor Medical Device Registration

R. Gotthardt
Rieke Gotthard
Advisor Medical Device Registration

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Schedule of Devices

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

Identification of the devices (Device name)	**Directive Certificate number to which this confirmation is made**	**Original expiry date as indicated on the Directive Certificate 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 and a written agreement signed**	**End date of extended validity / transition period (acc. to article 120.3a of the MDR)**
GeloRevoice/ GeloVox	3253DE414200610/ 3253GB414200610	27 May 2024	DNV MEDCERT GmbH 0482	DNV MEDCERT GmbH 0482	31 December 2028
GeloSitin					
Saseem					
NYDA express NYDA Läusespray NYDA plus					
LOYON					
Gepan instill	12770DE439190930/ 12770GB439190930 3253DE410200610/ 3253GB410200610	27 May 2024	DNV MEDCERT GmbH 0482	DNV MEDCERT GmbH 0482	31 December 2027

- End of list -