BOSCH + SOHN GmbH u. Co. KG · Bahnhofstraße 64, 72417 Jungingen, Germany · zentrale@boso.de

BOSCH +SOHN boso Manufacturer's Declaration in relation to Regulation (EU) 2023/607

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	BOSCH + SOHN GmbH u. Co. KG
Manufacturer address and contact details	Bahnhofstraße 64 72417 Jungingen, Germany
Single Registration Number (SRN)	DE-MF-000005958

Notified body name	DEKRA Certification GmbH Handwerkstraße 15 70565 Stuttgart, Germany
Notified body number	0124
Directive Certificate number to which this confirmation is made	No. 50539-17-05
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	2024-05-26
End date of extended validity/transition period	2028-12-31

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** 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,

Kommanditgesellschaft, Sitz Jungingen. AG Stuttgart HRA 420315.
Persönlich haftende Gesellschafterin: Boso Apparatebau Gesellschaft mit beschränkter Haftung, Sitz Jungingen. AG Stuttgart HRB 420192.
Geschäftsführer: Dipl.-Kfm. Kurt Rädle, Nadine Jauch

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above and 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covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

☒ Expired/expires *after* 20 March 2023:

☒ Formal applications to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment have been made or will be submitted by us to a notified body no later than 26 May 2024 for the devices listed in the attached schedule and signed written agreements will be 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.

➢ **Devices 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:

BOSCH + SOHN GmbH u. Co. KG
Jungingen, 2024-05-23

Kurt Rädle, CEO

BOSCH +SOHN boso Manufacturer's Declaration in Relation to Regulation (EU) 2023/607

Schedule of Devices

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

Identification of the devices (e.g., device name, family/group name device model or catalogue number)	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/contract signed	End date of extended validity / transition period
noninvasive aneroid sphygmomanometers - clinicus I - clinicus II - K I - K II - roid I - roid II - manuell - solid - classic - classico - varius - profitest - minimus - fix - nova S - varius privat - egotest - med I - BS 90	No. 50539-17-05	2024-05-26	DEKRA Certification GmbH No. 0124	DEKRA Certification GmbH No. 0124	2028-12-31

- classic privat - Ratiomed 602010 - Ratiomed 602010 E - Ratiomed 602020 - Ratiomed 602020 E					
noninvasive blood pressure units and systems - medicus - medicus system - medicus exclusive - medicus prestige S - medicus family - medicus family 4 - medicus vital - medicus X - medicus uno - medicus smart - medistar+	No. 50539-17-05	2024-05-26	DEKRA Certification GmbH No. 0124	DEKRA Certification GmbH No. 0124	2028-12-31
noninvasive blood pressure units and systems - boso ABI-system 100 - boso ABI-system 100 PWV	No. 50539-17-05	2024-05-26	DEKRA Certification GmbH No. 0124	DEKRA Certification GmbH No. 0124	2028-12-31
24-hour ambulatory blood pressure monitor - boso TM-2450 - boso TM-2450 cBP	No. 50539-17-05	2024-05-26	DEKRA Certification GmbH No. 0124	DEKRA Certification GmbH No. 0124	2028-12-31

BOSCH +SOHN boso Manufacturer's Declaration in Relation to Regulation (EU) 2023/607

Evaluation software for blood pressure units and systems - boso profil-manager XD	No. 50539-17-05	2024-05-26	DEKRA Certification GmbH No. 0124	DEKRA Certification GmbH No. 0124	2028-12-31
Thermometer, electronic - bosotherm basic - bosotherm flex	No. 50539-17-05	2024-05-26	DEKRA Certification GmbH No. 0124	DEKRA Certification GmbH No. 0124	2028-12-31
Thermometer, infrared - bosotherm diagnostic - bosotherm medical	No. 50539-17-05	2024-05-26	DEKRA Certification GmbH No. 0124	DEKRA Certification GmbH No. 0124	2028-12-31

BOSCH + SOHN GMBH U. CO. KG • POSTFACH 34 • D-72417 JUNGINGEN

EG-Konformitätserklärung für Medizinprodukte (Anhang V/VII MDD)
EC-Declaration of Conformity (Annex V/VII MDD)

Hiermit erklären wir
We, the undersigned

Bosch + Sohn GmbH u. Co KG
Bahnhofstraße 64
D-72417 Jungingen

in eigener Verantwortung, dass nachstehende Medizinprodukte
declare on our own authority that the referred medical devices below

Geräteart: *Product:*	**Nicht-invasives Blutdruckmesssystem** ***Non invasive blood pressure system***
Bezeichnung: *(Type)*	**boso ABI-system 100 PWV** **boso ABI-system 100**
Klassifizierung nach MDD: *Classification according MDD:*	**Klasse IIa** ***Class IIa***

den grundlegenden Anforderungen der nachfolgenden Richtlinie entsprechen
comply with the essential requirements of the following directive

Medizinprodukte Richtlinie 93/42/EWG
Medical Device Directive 93/42/EC

Name und Adresse der benannten Stelle, die am Konformitätsbewertungsverfahren beteiligt war
Name and address of the notified body being involved in the conformity assessment procedure

DEKRA Certification GmbH
Handwerkstraße 15
70565 Stuttgart

gekennzeichnet durch
marked

CE 0124

Gültig bis: **26.05.2024**
Valid until: ***26.05.2024***

zugehöriges Anhang V Zertifikat Reg. Nr: 50539-17-05
corresponding annex V certificate reg. no.: 50539-17-05

Jungingen, 27. April 2020
BOSCH+SOHN GMBH U. CO. KG

Hans-Peter Haug, Geschäftsführer
Hans-Peter Haug, CEO

BOSCH + SOHN GMBH U. CO. KG • POSTFACH 34 • D-72417 JUNGINGEN

EG-Konformitätserklärung für Medizinprodukte (Anhang V/VII MDD)
EC-Declaration of Conformity (Annex V/VII MDD)

Hiermit erklären wir
We, the undersigned

Bosch + Sohn GmbH u. Co KG
Bahnhofstraße 64
D-72417 Jungingen

in eigener Verantwortung, dass nachstehende Medizinprodukte
declare on our own authority that the referred medical devices below

Geräteart: Product:	**Auswertungssoftware** **evaluation software**
Bezeichnung: *(Type)*	**boso profil-manager XD**
Klassifizierung nach MDD: *Classification according MDD:*	**Klasse IIa** ***Class IIa***

den grundlegenden Anforderungen der nachfolgenden Richtlinie entsprechen
comply with the essential requirements of the following directive

Medizinprodukte Richtlinie 93/42/EWG
Medical Device Directive 93/42/EC

Name und Adresse der benannten Stelle, die am Konformitätsbewertungsverfahren beteiligt war
Name and address of the notified body being involved in the conformity assessment procedure

DEKRA Certification GmbH
Handwerkstraße 15
70565 Stuttgart

gekennzeichnet durch
marked by

CE 0124

Gültig bis: **26.05.2024**
*Valid until: **26.05.2024***

zugehöriges Anhang V Zertifikat Reg. Nr: 50539-17-05
corresponding annex V certificate reg. no.: 50539-17-05

Jungingen, 27. April 2020
BOSCH+SOHN GMBH U. CO. KG

Hans-Peter Haug, Geschäftsführer
Hans-Peter Haug, CEO

Kommanditgesellschaft, Sitz Jungingen. AG Stuttgart HRA420315.
Persönlich haftende Gesellschafterin: boso Apparatebau Gesellschaft mit beschränkter Haftung, Sitz Jungingen. AG Stuttgart HRB420192
Geschäftsführer: Dipl.-Kfm. Kurt Rädle, MBA Hans-Peter Haug