

EG - KONFORMITÄTSERKLÄRUNG EC - DECLARATION OF CONFORMITY

Für das nachstehend bezeichnete Medizinprodukt
For the following named medical device

Produktname Name of product:	Stethoskope, siehe Liste im Anhang Stethoscopes, see attached list
Basis UDI / basic UDI	426038196StethoskopGT
Hersteller / Manufacturer:	LUXAMED GmbH & Co. KG
Anschrift / Address:	Daniel-Weil-Straße 3 89143 Blaubeuren Germany

wird hiermit in alleiniger Verantwortung erklärt, dass es die Anforderungen der Verordnung (EU) 2017/745 (MDR) erfüllt und nach Anhang VIII, Regel 1, der Klasse I zugeordnet ist, nach Anhang I der Verordnung (EU) 2017/745 (MDR) alle anwendbaren grundlegenden Sicherheits- und Leistungsanforderungen erfüllen.
Gültig bis / Bis zur Änderung eines in der Tabelle genannten Produkte, längstens aber bis zum 22.04.2023.
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we declare in sole responsibility, that the provisions of Regulation (EU) 2017/745 which apply to them are fulfilled and according to annex VIII, rule 1, assigned to class I, according to Annex I of Regulation (EU) 2017/745 (MDR) meet all applicable basic safety and performance requirements.
Validity / Until the change of one of the products specified in the table, but at the latest until 22.04.2023.

Folgende angewandt harmonisierte Normen, nationale Normen oder andere normative Dokumente werden erfüllt:

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Following applied harmonised standards, national standards or other normative documents are fulfilled

(EU) 2017/745 (MDR)
EN ISO 13485



Blaubeuren, 2020-11-02

Matthias Dubb
QMB

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Produktliste

G1.212.114	LuxaScope Sonus Adult Flex, Edelstahl, Erwachsene für Wechselmembrane, schwarz
G1.212.214	LuxaScope Sonus Adult Flex, Edelstahl, Erwachsene für Wechselmembrane, navy blau
G1.212.314	LuxaScope Sonus Adult Flex, Edelstahl, Erwachsene für Wechselmembrane, grau
G1.112.114	LuxaScope Sonus Flat Flex, Aluminium, für Wechselmembrane, schwarz
G1.112.414	LuxaScope Sonus Flat Flex, Aluminium, für Wechselmembrane, rot
G1.112.514	LuxaScope Sonus Flat Flex, Aluminium, für Wechselmembrane, gelb
G5.212.174	Wechsel-Membrane zu LuxaScope Sonus Adult Flex & Sonus Flat Flex (1VE = 250 Stück)
G5.216.174	Wechsel-Trichter zu LuxaScope Sonus Flex (1VE = 250 Stück)
G1.211.114	LuxaScope Sonus Adult, Edelstahl, Erwachsene, schwarz
G1.211.914	LuxaScope Sonus Adult, Edelstahl, Erwachsene, weiss
G1.221.114	LuxaScope Sonus Pediatric, Edelstahl, Kinder/Neugeborene, schwarz
G1.221.914	LuxaScope Sonus Pediatric, Edelstahl, Kinder/Neugeborene, weiss
G1.411.114	LuxaScope Sonus Cardiology, Edelstahl, schwarz
G1.411.914	LuxaScope Sonus Cardiology, Edelstahl, weiss

Productlist

G1.212.114	LuxaScope Sonus Adult Flex, stainless steel for disposable diaphragm, Adult, black
G1.212.214	LuxaScope Sonus Adult Flex, stainless steel for disposable diaphragm, Adult, navy blue
G1.212.314	LuxaScope Sonus Adult Flex, stainless steel for disposable diaphragm, Adult, grey
G1.112.114	LuxaScope Sonus Flat Flex, Aluminium, for disposable diaphragm, black
G1.112.414	LuxaScope Sonus Flat Flex, Aluminium, for disposable diaphragm, red
G1.112.514	LuxaScope Sonus Flat Flex, Aluminium, for disposable diaphragm, yellow
G5.212.174	Disposable Diaphragm for LuxaScope Sonus Flex, 250 pieces (1 PU = 250 pcs.)
G5.216.174	Disposable Ring for LuxaScope Sonus Flex, 250 pieces (1 PU = 250 pcs.)
G1.211.114	LuxaScope Sonus Adult, stainless steel, adult, black
G1.211.914	LuxaScope Sonus Adult, stainless steel, adult, white
G1.221.114	LuxaScope Sonus Pediatric, stainless steel, for infants / newborns, black
G1.221.914	LuxaScope Sonus Pediatric, stainless steel, for infants / newborns, white
G1.411.114	LuxaScope Sonus Cardiology, stainless steel, black
G1.411.914	LuxaScope Sonus Cardiology, stainless steel, white