



**Edwards**

# EC Declaration of Conformity

Manufacturer: *Edwards Lifesciences LLC  
One Edwards Way  
Irvine, CA 92614, USA*

European Representative: *Edwards Lifesciences Services GmbH  
Edisonstraße 6  
85716 Unterschleißheim, Germany*

Product category: *Single Use Devices*

Product(-s): ***Hemodynamic Monitoring Disposables (non-DEHP/e-Beam)***  
*Model codes, Names: see following pages*

Classification: *Class IIa/ Rule 10 (According to Annex IX of the MDD)*

Conformity Assessment Route: *Annex II (excluding Annex II.4)*

UMDNS / GMDN Nomenclature: *See following pages*

Applicable Standard(-s): *See Essential Requirements Checklist of Technical File*

Start of CE Marking: *See following pages*

We herewith declare that the distributed CE marked products specified above conform to the product(s) covered by the "EC Certificate" issued and delivered by TÜV in accordance with Annex II of the "EC Directive", Council Directive 93/42/EEC, concerning Medical Devices. This declaration of conformity is issued under the sole responsibility of Edwards Lifesciences LLC. All supporting documentation is retained at the premises of the manufacturer.

In addition, we ensure and declare that the distributed CE marked products meet the provisions of the EC-Directives that apply to them.

The manufacturer has established and is maintaining a quality system which meets the requirements of EN ISO 13485:2016.

These directive(s) and standard(s) are supported by the following certificate(s):

Certificate Number	Valid until	Issued by	Holder of Certificate	Facility
G1 039555 0198	2024-05-26	TÜV SÜD Product Service	Edwards Lifesciences LLC, Irvine	Edwards Lifesciences LLC, Irvine*

\*Denotes Design and Development facility

Notified Body: *TÜV SÜD Product Service GmbH  
Ridlerstraße 65  
80339 München, Germany  
Identification Number 0123*

**Pressure Monitoring Kit/Set with TruWave™ Disposable Pressure Transducer with Non-DEHP (< 0.1%) Tubing**

*With TruWave Disposable Pressure Transducer:*

*UMDNS code: 16909, Transducer, pressure, single use (GMDN code: 35927)*

<b>Model Code</b>	<b>Description</b>	<b>Date CE Mark first Applied</b>
T100209B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T001650A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
PX284	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
PX260	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
PX272	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T100214A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T100215A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T001631A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T433803A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
PX3X3284C	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T001657A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
PX278C	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T001658A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T001709A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
PXMK2009	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
PX604I	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T005086A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
PX3X3	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
PX212	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T001619A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T001645A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
PX600I	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
PX2X2	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
PX3X3272	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018

**Pressure Monitoring Kit/Set with TruWave™ Disposable Pressure Transducer with Non-DEHP (< 0.1%) Tubing**

*With TruWave Disposable Pressure Transducer:*

*UMDNS code: 16909, Transducer, pressure, single use (GMDN code: 35927)*

<b>Model Code</b>	<b>Description</b>	<b>Date CE Mark first Applied</b>
T001758A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T001660A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T100212A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
PXCMK590	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
PXMK1940	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T100202A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
PX2X2284C	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T001712A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T494C00B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
PX284R	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T001724A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
PX266C	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T441T01C	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
PX3X3AN	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T322242B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
PXMK1070	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T531401A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
PXMK2011	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T450217A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
PX600	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T001775A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
PX284AN	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T321571A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T332J01A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T333F00A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018

**Pressure Monitoring Kit/Set with TruWave™ Disposable Pressure Transducer with Non-DEHP (< 0.1%) Tubing**

*With TruWave Disposable Pressure Transducer:*

*UMDNS code: 16909, Transducer, pressure, single use (GMDN code: 35927)*

<b>Model Code</b>	<b>Description</b>	<b>Date CE Mark first Applied</b>
PXMK1977	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
PXMK1299	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T001725A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T001624A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T328201A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T001702A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T005052A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
PX4X4	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T397704A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
PXMK2036	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T001789B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
PXMK2222	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T320544A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T447907A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
PXMK1714	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
PXMK1876	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
PXMK1970	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
PX200	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T323924C	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
PX2X2YB	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T440B21A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T410114B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T341212A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
PXCMK315	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
PXMK2010	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018

**Pressure Monitoring Kit/Set with TruWave™ Disposable Pressure Transducer with Non-DEHP (< 0.1%) Tubing**

*With TruWave Disposable Pressure Transducer:*

*UMDNS code: 16909, Transducer, pressure, single use (GMDN code: 35927)*

<b>Model Code</b>	<b>Description</b>	<b>Date CE Mark first Applied</b>
T530219A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T005002A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T581203B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T349301B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T491Y01B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T322238A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T413406A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T530310A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T005025A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T441809C	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T333919A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
PXMK0658	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T334402A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
PXMK0976	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
PXMK1063	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
PXMK1183	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
PXMK1326	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
PXMK1350	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
PXMK1360	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T433204B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
PXMK1577	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
PXMK1696	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
PXMK1724	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
PXMK1805	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
PXMK1849	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018

**Pressure Monitoring Kit/Set with TruWave™ Disposable Pressure Transducer with Non-DEHP (< 0.1%) Tubing**

*With TruWave Disposable Pressure Transducer:*

*UMDNS code: 16909, Transducer, pressure, single use (GMDN code: 35927)*

<b>Model Code</b>	<b>Description</b>	<b>Date CE Mark first Applied</b>
PXMK2002	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T433202B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
PXMK2147	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T333C00A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
PXMK2242	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
PXMK2306	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
PXMK2327	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
PXMK287	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T333918A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T330V11A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T432105A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T001713A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T001797B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T005004A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T321573A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T322256A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T325202A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T328500A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T334041A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T397705B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T413670A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T433801A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T443422A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T493Y02B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
T495009A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018

**Pressure Monitoring Kit/Set with TruWave™ Disposable Pressure Transducer with Non-DEHP (< 0.1%) Tubing**

*With TruWave Disposable Pressure Transducer:*

*UMDNS code: 16909, Transducer, pressure, single use (GMDN code: 35927)*

<b>Model Code</b>	<b>Description</b>	<b>Date CE Mark first Applied</b>
T530116B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
PX600F	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	5/4/2018
PXMK1077	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	8/23/2018
PXMK2056	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	8/23/2018
PXMK1640	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	8/23/2018
PXMK1159	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	8/23/2018
PXMK2137	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	8/23/2018
PXMK1780	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	8/23/2018
PXMK0033	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	8/23/2018
PXMK1256NS	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	8/23/2018
PXMK1749	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	8/23/2018
T310197A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	8/23/2018
T331U03C	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	8/23/2018
PXMK0036	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	8/23/2018
T442J00A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	8/23/2018
PXMK1300	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	8/23/2018
PXMK2331	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	8/23/2018
T395606B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	8/23/2018
T310195A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	8/23/2018
T320564A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	8/23/2018
T349302A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	8/23/2018
T431514C	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	8/23/2018
T433201A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	8/23/2018
T001633A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	8/28/2018
T337119B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	8/28/2018
PXMK9146	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	8/28/2018

**Pressure Monitoring Kit/Set with TruWave™ Disposable Pressure Transducer with Non-DEHP (< 0.1%) Tubing**

*With TruWave Disposable Pressure Transducer:*

*UMDNS code: 16909, Transducer, pressure, single use (GMDN code: 35927)*

<b>Model Code</b>	<b>Description</b>	<b>Date CE Mark first Applied</b>
T001786A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	8/28/2018
T530217B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	8/28/2018
PXMK575	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	8/28/2018
PXMK2277	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	8/28/2018
PX601	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	8/28/2018
PXMK2016	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	8/28/2018
PX600F30	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	8/28/2018
PX604	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	8/28/2018
PXMK478	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	8/28/2018
T005005A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	8/28/2018
T337305B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	8/28/2018
T005080A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	8/28/2018
T310682A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	8/28/2018
T321570A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	8/28/2018
T330831A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	8/28/2018
T395705A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	8/28/2018
T413675A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	8/28/2018
T430142A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	8/28/2018
T440B20B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	8/28/2018
T461803B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	8/28/2018
T492011A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	8/28/2018
T530317A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	8/28/2018
T531900A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	8/28/2018
T581201F	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	8/28/2018
PXMK1935	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	1/16/2019
PXMK0010	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	1/16/2019

<b>Pressure Monitoring Kit/Set with TruWave™ Disposable Pressure Transducer with Non-DEHP (&lt; 0.1%)Tubing</b>		
<i>With TruWave Disposable Pressure Transducer:</i> UMDNS code: 16909, Transducer, pressure, single use (GMDN code: 35927)		
<b>Model Code</b>	<b>Description</b>	<b>Date CE Mark first Applied</b>
PXMK0011	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	1/16/2019
PXMK0013	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	1/16/2019
PXMK0014	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	1/16/2019
T610002A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	1/16/2019
PXMK1267	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	6/14/2019
T312306A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	6/14/2019
T270900A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	6/14/2019
T321572A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	6/14/2019
T322247A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	6/14/2019
T323923A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	6/14/2019
T331F06B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	6/14/2019
T391608B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	6/14/2019
T430139A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	6/14/2019
T430177B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	6/14/2019
T430609A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	6/14/2019
T440907B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer)	6/14/2019

<b>Pressure Monitoring Kit/Set with VAMP Plus with non-DEHP Tubing</b>		
<i>With TruWave Disposable Pressure Transducer:</i> Class IIa / Rule 10 UMDNS code: 16909, Transducer, pressure, single use (GMDN code: 35927);		
<i>With VAMP:</i> Class IIa/ Rule 10 UMDNS code: 10446, Blood sampling kit (GMDN code: 31336)		
<b>Model Code</b>	<b>Description</b>	<b>Date CE Mark first applied</b>
PXVP2284	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	8/23/2018
T001691A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	8/23/2018
PXVP2272	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	8/23/2018
PXVP2284AT3	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	8/23/2018

<b>Pressure Monitoring Kit/Set with VAMP Plus with non-DEHP Tubing</b> <i>With TruWave Disposable Pressure Transducer:</i> Class IIa / Rule 10 UMDNS code: 16909, Transducer, pressure, single use (GMDN code: 35927);  <i>With VAMP:</i> Class IIa/ Rule 10 UMDNS code: 10446, Blood sampling kit (GMDN code: 31336)		
PXVP2284DZ	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	8/23/2018
PXVP2260	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	8/23/2018
PXVP0566	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	8/23/2018
PXVP1087	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	8/23/2018
T336548B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	8/23/2018
PXVP1073	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	8/23/2018
PXVP0778	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	8/23/2018
T005074A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	8/23/2018
PXVP1072	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	8/23/2018
PXVP0765	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	8/23/2018
T451702A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	8/23/2018
PXVP0861	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	8/23/2018
PXVP0843	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	8/23/2018
PXVP1089	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	8/23/2018
PXVP1107	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	8/23/2018
PXVP2X2AT3	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	8/23/2018
PXVP23X3AT3	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	8/23/2018
PXVP1071	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	8/23/2018
T100671B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	8/23/2018
PXVP0549	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	8/23/2018
PXVP1066	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	8/23/2018
PXVP3X3DZ	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	8/23/2018
T451703A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	8/23/2018
PXVP0550	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	8/23/2018
PXVP23X3	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	8/23/2018

**Pressure Monitoring Kit/Set with VAMP Plus with non-DEHP Tubing***With TruWave Disposable Pressure Transducer:*

Class IIa / Rule 10

UMDNS code: 16909, Transducer, pressure, single use (GMDN code: 35927);

*With VAMP:*

Class IIa/ Rule 10

UMDNS code: 10446, Blood sampling kit (GMDN code: 31336)

PXVP24X4AT3	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	8/23/2018
T001765A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	8/28/2018
T001759A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	8/28/2018
T391T01A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	8/28/2018
T001760A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	10/25/2018
T326207B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	10/25/2018
T336547B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	10/25/2018
T336546B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	10/25/2018
T391T00A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	10/25/2018
T432618G	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	10/25/2018
PXVPL0029	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	10/25/2018
T490007A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	10/25/2018
PXVPL0031	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	10/25/2018
T001691M	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	10/25/2018
T100671M	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	10/25/2018
T430023M	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	10/25/2018
T398807D	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	4/26/2019
T398808A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	4/26/2019
T397708A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	4/26/2019
T001760A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	4/26/2019
T326207B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	4/26/2019
T336547B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	4/26/2019
T336546B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Plus)	4/26/2019

**Pressure Monitoring Kit/Set with VAMP Adult with non-DEHP Tubing***With TruWave Disposable Pressure Transducer:*

Class IIa / Rule 10

UMDNS code: 16909, Transducer, pressure, single use (GMDN code: 35927);

*With VAMP:*

Class IIa/ Rule 10

UMDNS code: 10446, Blood sampling kit (GMDN code: 31336)

<b>Model Code</b>	<b>Description</b>	<b>Date CE Mark first applied</b>
T490009M	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
PXAVMP	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
PXAVMP3	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
PXVK0398	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
PXVK0412	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
PXVK0467	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
PXVK0670	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
PXVK0755	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
PXVK0797	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
PXVK0802	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
PXVK0853	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
PXVK0996	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
PXVK1079	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
PXVK1099	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
PXVK220	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
PXVK225	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
PXVK268	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
PXVMP120	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
PXVMP160	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
PXVMP172	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
PXVMP172AT3	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
PXVMP184	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
PXVMP260	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
PXVMP272	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018

<b>Pressure Monitoring Kit/Set with VAMP Adult with non-DEHP Tubing</b> <i>With TruWave Disposable Pressure Transducer:</i> Class IIa / Rule 10 UMDNS code: 16909, Transducer, pressure, single use (GMDN code: 35927);  <i>With VAMP:</i> Class IIa/ Rule 10 UMDNS code: 10446, Blood sampling kit (GMDN code: 31336)		
PXVMP2X21	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
PXVMP2X22	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
PXVMP2X31	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
PXVMP3X31	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
PXVMP3X32	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
T001670A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
T001671A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
T001673A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
T001737A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
T001741M	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
T001741A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
T001743A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
T001744M	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
T001744A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
T001745A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
T001746A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
T005048B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
T005049B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
T100500A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
T100504A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
T321811Z	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
T430140A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
T430178B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
T430179A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
T430180A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018

<b>Pressure Monitoring Kit/Set with VAMP Adult with non-DEHP Tubing</b> <i>With TruWave Disposable Pressure Transducer:</i> Class IIa / Rule 10 UMDNS code: 16909, Transducer, pressure, single use (GMDN code: 35927);  <i>With VAMP:</i> Class IIa/ Rule 10 UMDNS code: 10446, Blood sampling kit (GMDN code: 31336)		
T430181A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
T431305A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
T432104B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
T432703A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
T433806A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
T434303A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
T434304A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
T434500B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
T434501B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
T449103B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
T450544A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
T450545A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
T770000A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
T770002A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
T770003A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
PXVK0386	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
PXVK0387	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
PXVK0388	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
PXVK0437	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
PXVK0478	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
PXVK0789	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
PXVK1075	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
PXVK1076	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	10/25/2018
T005049B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	4/26/2019
T430180A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	4/26/2019

**Pressure Monitoring Kit/Set with VAMP Adult with non-DEHP Tubing***With TruWave Disposable Pressure Transducer:*

Class IIa / Rule 10

UMDNS code: 16909, Transducer, pressure, single use (GMDN code: 35927);

*With VAMP:*

Class IIa/ Rule 10

UMDNS code: 10446, Blood sampling kit (GMDN code: 31336)

T432104B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	4/26/2019
T449103B	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	4/26/2019
T321811Z	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	4/26/2019
T431305A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	4/26/2019
T770003A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	4/26/2019
T430179A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	4/26/2019
T001746A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	4/26/2019
T430140A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	4/26/2019
T432703A	Pressure Monitoring Set (w/TruWave Disposable Pressure Transducer & VAMP Adult)	4/26/2019