

該 非 判 定 書

作成責任者

横浜市戸塚区名瀬町 763-3-708

柚木行政書士事務所

代表・行政書士 柚木 勇

登録 10090102

045-567-6770 / 090-6171-7744



対象貨物・役務

高速液体クロマトグラフ (HPLC)

Waters 社製 Alliance 2690

判定 (2019.1.9 施行法令準拠)

輸出令別表第一の 1 項～15 項 対象外

同 16 項 該当

外為令別表の 1 項～15 項 対象外

同 16 項 対象外

判定理由

対象貨物は、分析装置の一種で、液体クロマトグラフである。液体に溶解した成分の分析に用いる簡便な装置である。机上に乗るサイズでありながら、4 種の溶剤を使い分けるマネジメントシステムや多数の試料を自動分析するシステムが一体化されていることが特徴である。

輸出令について

輸出を規制される品目は、輸出令別表第一の 1 項～15 項に限定列挙されているところ、液体クロマトグラフは、同表に掲げられた貨物ではない。よって、対象貨物は輸出令別表第一の 1 項～15 項について対象外と判定する。

外為令について

対象貨物には、いかなる技術情報・データも付属しない。よって、外為令については対象外と判定する。

添付資料

1. 項目別対比表 (全1頁)
2. 対象貨物資料 (全8頁)

輸出貿易管理令 別表第一 項目別対比表 (該非判定用)

輸出令別表第一で明らかに規制されていない貨物

貨物名：高速液体クロマトグラフ (HPLC)
メーカー名：Waters
型及び銘柄：Alliance 2690

2019.1.9 施行法令準拠

輸出令別表第一関連	判定欄 (いずれかをマーク)	貨物の内容・理由等
輸出令別表第一の1～15の項 及び 貨物等省令第1条から第14条 に該当する貨物か？	☐ はい ☒ いいえ	高速液体クロマトグラフは、別一の1項～15項に掲げられていない

注意事項

※ 判定欄で「はい」にチェックした場合は、関係する項目別対比表で、該非判定をすること。本シートは使用できない。

※ 判定欄で「いいえ」にチェックした場合でも、食品や木材等を除き、輸出令別表第三(ホワイト国)以外に輸出する場合は、キャッチオール規制(用途・需要者)について確認すること。

作成責任者：(作成年月日：令和元年5月10日)

会社名 柚木行政書士事務所

所属・役職 行政書士・STC Associate

(フリガナ) ユノキ イサム

氏名 柚木 勇

電話 045-567-6770



1.1 Separations Module Overview

Factory Configurations

The Waters 2690 Separations Module is available from Waters in a number of configurations, differing from each other by the options that are included. These options are described in [Section 1.5, Options and Accessories](#). The two *primary* configurations are designated:

- **2690** – Provides quaternary solvent, high-performance solvent delivery, integral helium sparge for solvent conditioning, integral plunger seal-wash system, 120-vial capacity sample management system, liquid-crystal display and keyboard user interface, and floppy disk drive.
- **2690 XE** – Provides the capabilities of the 2690 base product, replaces the helium sparge system with a four-channel in-line vacuum degasser, and adds a column heater and a sample heater/cooler.

HPLC System Configurations

The Separations Module supports RS-232, IEEE-488, and I/O connections for compatibility with a variety of HPLC system configurations. The Separations Module can function as:

- The source of I/O and timing signals in a simple, stand-alone HPLC system
- The IEEE-488 system controller in a stand-alone HPLC system using a Waters 2410 or 410 Refractive Index Detector and/or a Waters 2487 or 486 Tunable Absorbance Detector
- A component of an HPLC system controlled by the Millennium[®] Chromatography Manager, the Micromass MassLynx[®] software, or a data system using RS-232 communications

Control of Chromatographic Parameters

The Separations Module controls:

- Method programming
- Solvent composition
- Flow rate
- Plunger seal wash flow
- Sample injection
- External events
- Operation of detectors over the IEEE-488 interface bus

Appendix A

Specifications

This appendix includes specifications for the following:

- Physical
- Environmental
- Electrical
- Solvent management system
- Sample management system
- Instrument control and communication

Table A-1 Physical Specifications

Item	Specification
Height	22.5 in. (57.1 cm)
Depth	22.5 in. (57.1 cm); 25.5 in. (64.8 cm) with optional sample heater/cooler
Width	18 in. (45.7 cm); 23.0 in. (58.4 cm) with optional column heater
Weight	Optional bar code reader adds 1.5" (3.8 cm) to overall width 100 lb (45.5 kg) 130 lb (59.1 kg) with optional sample heater/cooler and column heater
Wetted Surface Materials	316 stainless steel, zirconia ceramic, UHMWPE, sapphire, ruby, Tefzel [®] (ETFE), Teflon [®] (FEP and PTFE), Fluoroloy G, Fluoroloy-08R

Table A-2 Environmental Specifications

Item	Specification
Operating Temperature	4 to 40 °C
Relative Humidity	20 to 80%, noncondensing
Acoustic Noise	<65 dB(A)
Solvent Compatibility (see Section D.2, Solvent Compatibility)	Solvents consistent with materials of construction. Salts and buffers can reduce seal life, especially at pressures in excess of 3000 psi.

Table A-3 Electrical Specifications

Item	Specification
Power Requirements	950 VA (maximum)
Line Voltage	85 to 132 or 180 to 264 VAC
Frequency	47 to 63 Hz
Fuse (for units with 400 W power supply only)	10 A, fast-blow, 110 VAC nominal, ANSI; 6.3 A, fast-blow, 220 VAC nominal, IEC
Time or user-controllable switch closures S1 – S4	Four controllable contact closures (two terminals per closure). Maximum allowable current = 0.5 A per contact. Maximum allowable voltage = 30 VDC. Contact resistance = 0.2 ohms. Outputs can be controlled from the I/O Events Table or directly from the front panel. Two modes available from front panel and I/O Events table: On = contact closed; Off = contact open. Additional modes available in the I/O Events table: Pulse = single contact closure for programmable period; Toggle = changes the current state.

Table A-3 Electrical Specifications (Continued)

Item	Specification
Stop Flow (input)	Two terminals (+, –) that allow other LC devices to immediately stop solvent flow. User-selectable to halt flow on high or low signal. Input voltage range: ± 30 VDC. Logic high = >3.0 VDC $\pm 10\%$, logic low = <1.9 VDC $\pm 10\%$. Minimum pulse width = 10 msec.
Hold Inject (input)	Two sets of (+, –) terminals that allow other LC devices to delay an injection. Boolean operator selects whether one or both inputs delay the injection. Input voltage range: ± 30 VDC. Logic high = >3.0 VDC $\pm 10\%$, logic low = <1.9 VDC $\pm 10\%$. Minimum pulse width = 10 msec.
Chart Output	Two terminals (+, –) for recording the following user-selectable outputs: • Programmed flow rate • Sample loop pressure • System pressure • Primary head pressure • Programmed composition (%A, %B, %C, %D) • Sample temperature • Column temperature • Degasser vacuum (relative, absolute)
Run Stopped	Contact closure indicating: • Sample set is suspended • Current function is suspended Maximum allowable current = 0.5 A. Maximum allowable voltage = 30 VDC. Contact resistance = 0.2 ohms.
Inject Start	Contact closure (across terminals 1 and 2) for 1 sec on injection. Maximum allowable current = 0.5 A. Maximum allowable voltage = 30 VDC. Contact resistance = 0.2 ohms.

Table A-3 Electrical Specifications (Continued)

Item	Specification
Ground Terminals	Connected to signal ground and used as reference for outputs

Table A-4 Solvent Management System Specifications—2690 XE Configuration

Item	Specification
Number of Solvents	One to four
Solvent Conditioning	Vacuum degas, two (2) operating modes, four (4) chambers, ≈ 10 mL internal volume per chamber or Helium sparge, four (4) independent channels, programmable flow rate for initial and maintenance periods
Programmable Flow Rate Range	0.000 and 0.010 to 10.000 mL/min in 0.001-mL/min. increments
Typical Operating Flow Rate Range	0.050 to 5.000 mL/min in 0.001-mL/min increments
Compressibility Compensation	Automatic and continuous
Effective System Delay Volume	<650 μ L, independent of backpressure @ 1 mL/min
Plunger Seal Wash	Integral, active, programmable
Gradient Profiles	Eleven (11) gradient curves [including linear, step (2 curves), concave (4 curves), and convex (4 curves)]
Dry Prime/Wet Prime	Automatic, front panel control
Flow Ramping	Time (0.01 to 30.00 min in 0.01-min increments) to reach maximum flow rate

Table A-4 Solvent Management System Specifications–2690 XE
Configuration (Continued)

Item	Specification
Maximum Operating Pressure	5000 psi (345 bar) (0.010 to 3.000 mL/min) Programmable upper and lower limits. Pressure fall-off at >3.000 mL/min.
Pressure Ripple	±2.5% (1 mL/min, degassed methanol, at 1700 psi backpressure)
Composition Range	0.0 – 100.0 in 0.1% increments
Composition Accuracy	±0.5% absolute, independent of backpressure (Proportioning Valve Pair Test [degassed methanol:methanol/propylparaben, 2 mL/min, 254 nm])
Composition Precision	0.15% RSD or 0.02 min SD, whichever is greater, based on retention time. (Degassed methanol:water 60:40 Dial-a-Mix, 1 mL/min, six replicates, phenone mix, 254 nm.)
Flow Precision	0.075% RSD or 0.02 min SD, based on retention time (N = 6) or volumetric measures (0.200 to 5.000 mL/min), isocratic premix
Flow Accuracy	±1% or 10 µL/min, whichever is greater, (0.200 to 5.000 mL/min), degassed methanol, at 600 psi backpressure

Table A-5 Sample Management System Specifications

Item	Specification
Number of Sample Vials	120 vials, configured in 5 carousels of 24 vials each
Number of Sample Injections	1 to 99 injections per sample vial
Sample Delivery Precision	Typically <0.5% RSD, 5 to 80 µL. (Degassed methanol:water 60:40 Dial-a-Mix, 1 mL/min, six replicates, phenone mix, 254 nm.)

Table A-5 Sample Management System Specifications (*Continued*)

Item	Specification
Sample Carryover	<0.1%
Injection Accuracy	$\pm 1 \mu\text{L}$ ($\pm 2\%$), 50 μL , N = 6. Sample is degassed water, analytical solvent is degassed methanol.
Standard Sample Vial	2 mL
Sample Temperature Control (Optional)	4 to 40 °C, programmable in 1 °C increments
Advanced Operations	Stat runs, auto additions, auto standards
Injection Volume Range	0.1 to 100 μL , standard; 0.1 to 2000 μL , with optional sample loop
Injector Linearity	>0.999 coefficient of deviation (1 to 100 μL)

Table A-6 Instrument Control and Communication Specifications

Item	Specification
Column Heater (Optional)	20 °C (5 °C above ambient) to 60 °C, in 1 °C increments
IEEE-488 Interface	Control of Waters IEEE-488 equipped detectors; communication with Millennium Chromatography Manager workstations or MicroMass detectors using MassLynx software
RS-232 Interface (Ports A and B)	Output of ASCII text files to a printer/PC/integrator (Port A) Bidirectional ASCII communications with data systems (Port B)
BCD Output (optional)	At injection, sends vial position to an external LIMS

Table A-6 Instrument Control and Communication Specifications *(Continued)*

Item	Specification
Bar Code Reader (optional)	Sends vial data to a configured printer, integrator, or diskette with other 2690 Per-inject data. If the 2690 Separations Module is controlled by Millennium ³² software, vial data appears in a special bar code custom field.
Floppy Disk Drive	1.44 MB, 3.5-inch disk, for methods transfer and archiving; reportable GLP log