
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM SD

Specialized Disclosure Report

NUWELLIS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

001-35312

(Commission File Number)

No. 68-0533453

(I.R.S. Employer Identification Number)

12988 Valley View Road, Eden Prairie, MN 55344

(Address of principal executive offices) (Zip code)

Nestor Jaramillo, Jr. (952) 345-4200

(Name and telephone number, including area code, of person to contact in connection with this report)

Check the appropriate box to indicate the rule pursuant to which this form is being filed, and provide the period to which the information in this form applies:

Rule 13p-1 under the Securities Exchange Act (17 CFR 240.13p-1) for the reporting period from January 1, 2020 to December 31, 2020.

Section 1 - Conflict Minerals Disclosure

Item 1.01 Conflict Minerals Disclosure and Report

This Form SD of Nuwellis, Inc. (the “**Company**”) is filed pursuant to Rule 13p-1 promulgated under the Securities Exchange Act of 1934, as amended, for the reporting period January 1, 2020 to December 31, 2020.

A copy of the Company’s Conflict Minerals Report is provided as Exhibit 1.01 to this Form SD, and is publicly available in the Investor section of the Company’s website at www.nuwellis.com, by selecting Financials & Filings under the Investors tab.

Item 1.02 Exhibit

A copy of the Company’s Conflict Minerals Report is provided as Exhibit 1.01 to this Form SD and incorporated herein by reference.

Section 2 - Exhibits

Item 2.01 Exhibits

The following exhibit is filed as part of this report.

Exhibit	Description
1.01	Conflict Minerals Report of Nuwellis, Inc.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the duly authorized undersigned.

NUWELLIS, INC.

By: /s/ Nestor Jaramillo, Jr.
Nestor Jaramillo, Jr.
President, Chief Executive Officer and Chief Financial Officer

May 27, 2021
(Date)

NUWELLIS, INC.
Conflict Minerals Report

For the reporting period from January 1, 2020 to December 31, 2020

Background

This Conflict Minerals Report (this **“Report”**) of Nuwellis, Inc. (**“we”**, **“us”** or the **“Company”**) has been prepared pursuant to Rule 13p-1 and Form SD (the **“Rule”**) promulgated under the Securities Exchange Act of 1934, as amended, for the reporting period January 1, 2020 to December 31, 2020.

The Rule imposes certain reporting obligations on companies who manufacture or contract to manufacture products containing certain specified minerals that are necessary to the functionality or production of the Company’s products. The specified minerals, which we collectively refer to in this Report as the **“Conflict Minerals,”** are gold, columbite-tantalite (coltan), cassiterite and wolframite, including their derivatives, which are limited to tantalum, tin and tungsten (**“3T”**). The **“Covered Countries”** for the purposes of the Rule and this Report are the Democratic Republic of the Congo, the Republic of the Congo, the Central African Republic, South Sudan, Uganda, Rwanda, Burundi, Tanzania, Zambia and Angola.

This Report relates to the process undertaken by the Company for the Company’s products that contain Conflict Minerals and were manufactured, or contracted to be manufactured, during calendar year 2020.

Company Overview

We are a medical device company dedicated to changing the lives of patients suffering from fluid overload through science, collaboration, and innovative technology. The company is focused on developing, manufacturing, and commercializing medical devices used in ultrafiltration therapy, including the Aquadex FlexFlow® and the Aquadex SmartFlow™ systems (collectively referred to herein as the **“Aquadex System”**). The Aquadex SmartFlow™ system is indicated for temporary (up to eight hours) or extended (longer than 8 hours in patients who require hospitalization) use in adult and pediatric patients weighing 20kg or more whose fluid overload is unresponsive to medical management, including diuretics.

The Aquadex System consists of: (i) a console, a piece of capital equipment containing electromechanical pumps and an LCD screen (the **“Console”**), (ii) a one-time disposable blood set (the **“Aquadex Blood Set”**), an integrated collection of tubing, filter, sensors, and connectors that contain and deliver the blood from and back to the patient, and (iii) a disposable catheter (the **“Aquadex Catheter”**), a small, dual-lumen catheter designed to access the peripheral venous system of the patient and to simultaneously withdraw blood and return filtered blood to the patient. Conflict Minerals are necessary to the functionality or production of certain critical components of the Aquadex System (the **“Covered Products”**) that were manufactured, or contracted to be manufactured, by the Company during calendar year 2020.

Manufacturing of the Console, Aquadex Blood Set and Aquadex Catheter during 2020

As of the third quarter of 2018, we manufacture all of the Covered Products in-house in our Eden Prairie, Minnesota facility.

The Company's Due Diligence Process

The Company formed a cross-functional team to address Conflict Minerals in the supply chain for the Aquadex System. This team included the Chief Technology Officer, Quality Assurance Manager and other members of the Quality and Operations organization. This team conducted a good faith reasonable country of origin inquiry ("**RCOI**") to identify and trace Conflict Minerals in the Company's supply chain, using procedures and tools recommended or provided by the Responsible Minerals Initiative (formerly the Conflict-Free Sourcing Initiative) and the Organisation for Economic Cooperation and Development Due Diligence Guidance for Responsible Supply Chain of Minerals from Conflict-Affected and High Risk Areas: Third Edition, including the related supplements on gold, tin, tantalum and tungsten (the "**OECD Guidance**").

This RCOI was reasonably designed to determine whether any of the Conflict Minerals originated in the Covered Countries and whether any of the Conflict Minerals may be from recycled or scrap sources. The Company does not purchase Conflict Minerals directly from mines, smelters or refiners; rather the Company contracts to manufacture products from materials and compounds acquired from third parties. The supply chain for the Covered Products is complex, and there are many third parties in the supply chain between the ultimate manufacturer of the Covered Products and the original sources of Conflict Minerals. Therefore, the Company must rely, and has relied, on its suppliers to provide information in their responses to the Company's inquiries regarding the existence of Conflict Minerals in any materials or products supplied to the Company and the source of such Conflict Minerals, if any.

The Company's direct suppliers are similarly reliant upon information provided by their suppliers. Our measures can provide only reasonable, not absolute, assurance regarding the source and chain of custody of the necessary Conflict Minerals.

The Company determined that nineteen suppliers were within the scope of the Company's RCOI during calendar year 2020 and contacted all nineteen suppliers, requesting that such suppliers provide Conflict Minerals data by completing the Conflict Mineral Reporting Template, a supply chain survey tool provided by the Responsible Minerals Initiative. The Company's reviewed the information received from such suppliers.

Results of Due Diligence Process

The Company received responses from nine suppliers. Four suppliers confirmed that no Conflict Minerals contained in the components supplied to the Company are sourced from a Covered Country. Two suppliers responded that 3T included in its product line is sourced from Covered Countries. Three suppliers responded that they are not able to determine whether any of the 3T and/or gold in its product line originates from a Covered Country since, to their knowledge, no refiners were sourcing from a Covered Country, but they did not receive responses from all of their suppliers and/or have not identified all of their suppliers.

The Company did not receive a response from ten suppliers. The Company is unable to determine the facilities used to process or the country of origin of all of the necessary Conflict Minerals in the products provided by its suppliers. The Company does not believe it has significant leverage with its existing suppliers, given the minimal amount of purchases relative to the size of the suppliers, to have an impact on the purchasing and sourcing decisions of its suppliers.

Further Efforts

The Company has yet to adopt a formal policy relating to the Conflict Minerals that incorporates the standards set forth in the OECD Guidance, although it has implemented certain provisions in practice. The Company generally is committed to the responsible sourcing of materials of its products and supports greater transparency with regard to its supply chain but is taking a reasonable, measured approach in responding to the requirements of the Rule.

The Company expects to take the following steps, among others, to improve its due diligence measures and to further mitigate the risk that the necessary Conflict Minerals contained in the Company's products finance or benefit armed groups in the Covered Countries: (i) continuing to identify any products that the Company manufactures or contracts to manufacture that contain Conflict Minerals; (ii) continuing to engage with suppliers to obtain current, accurate and complete information about the supply chain; and (iii) following up appropriately when information provided by suppliers appears to be incomplete or inaccurate. As noted above, the Company's efforts and impact are limited due to its minimal purchasing relative to the size of its suppliers.
